EXHIBIT 1

US FDA Clinical Data Summary of the Simon Nitinol Filter®

The following is a non-published summary of a non-randomized, prospective clinical study sponsored by NMT Medical, Inc. (Nitinol Medical Technologies, Inc.) of the Simon Nitinol Filter® for the prevention of recurrent pulmonary embolism. The purpose of the investigation was to confirm filter design and to develop safety and effectiveness data to support a 510(k) submission for approval by the United States Food & Drug Administration (FDA). This clinical investigation was conducted according to a written protocol and in compliance with US Good Clinical Practices regulations. The Simon Nitinol Filter received FDA 510(k) approval in July 1989. All data referenced are on file at NMT Medical.

Abstract

From February 1988 through November 1990, 258 patients underwent percutaneous placement of the Simon Nitinol Filter in 23 clinical sites in the United States. Follow-up studies mandated clinical evaluation and abdominal radiography; US, MR, and CT were optional. The final clinical results in 180 patients (70%) who completed the 6-month follow-up are analyzed, and significant adverse events during and beyond the 6 month trial period are reported. The data obtained from the trial were analyzed to determine if they adequately demonstrated the safety and effectiveness of the device. The Simon Nitinol Filter demonstrated excellent safety and effectiveness characteristics in protecting at-risk patients from the potentially serious consequences of recurrent pulmonary embolism. The filter was successfully inserted percutaneously via the femoral, jugular or antecubital route in all patients. Symptomatic recurrent pulmonary embolism was demonstrated in 1.2% of patients, and additional asymptomatic emboli were documented in 0.8% of patients. Symptomatic vena caval occlusions occurred in 8.1% and asymptomatic caval occlusions in an additional 1.6% by MR imaging. Filter migration (0.8%) was low and all cases were asymptomatic. The SNF is efficacious and has low morbidity. Its small introducer, two-level filtering, multiple access sites and MRI compatibility are advantageous.

Introduction

A clinical study was performed to assess the safety and effectiveness of the Simon Nitinol Filter® (SNF). The study enrolled 258 patients at risk of pulmonary embolism. Patients were enrolled at 23 clinical sites and the available data from these centers were compiled for purposes of evaluating the filter's safety and effectiveness.

Each patient enrolled in the study was followed up immediately after filter insertion and at 3 and 6 months post implantation. The data that were collected for each patient included the following: preexisting conditions, previous treatment, primary and secondary indications, procedural difficulties, and complications (major misplacement, migration, occlusion, pulmonary embolism and death). In addition, major complications were reported to the sponsor as they occurred. The sponsor also contacted investigators by telephone to assure that all significant problems and complications were reported.

The data obtained from the trial were analyzed to determine if they adequately demonstrated the safety and effectiveness of the device.

Device Description

The Simon Nitinol Filter represents a new generation of venous interruption devices designed to prevent recurrent pulmonary embolism. It is primarily indicated for patients who cannot, for a variety of reasons, be treated with anticoagulants. The unique design and material of the Simon Nitinol Filter provide excellent filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer with minimal entry site difficulties. The filter may be placed in the right or left femoral, jugular, subclavian or antecubital vein. The placement procedure is quick and simple to perform.

Compared to other filters, the SNF has the thermal shape-memory properties of nitinol, an alloy of nickel and titanium, that allow it to exist as a straightened set of wires when cooled within the storage tube or delivery catheter, and to transform into its predetermined filter shape when warmed to body temperature within the vena cava. The Simon Nitinol Filter has the advantages of a small (7 French I.D.) introducer size, two-level filtering, and MR imaging compatibility.

Clinical Investigation

This report of the clinical investigation includes the entire 258 patient study population. The parameters that were evaluated included occlusion characteristics, ease and success of insertion, prevention of recurrent pulmonary embolism, and incidence of migration and perforation as well as other adverse events.

Study Objectives

The objectives of the study included:

a. To assess the ease of filter insertion and placement.

b. To assess the security of filter anchorage as measured by lack of filter migration.

c. To assess the clinical complications of the filter both during the insertion procedure and in the postinsertion period. Complications evaluated included such events as minor complications related to the insertion procedure and occlusion of the filter. Major events such as filter migration, perforation and recurrent pulmonary embolism were likewise evaluated.

d. To assess clot-filtering effectiveness of the filter as measured by lack of recurrent pulmonary embolism.

The Simon Nitinol Filter is intended for use in the prevention of life-threatening pulmonary emboli in those patients at risk for pulmonary embolism or with a history of recurrent

pulmonary embolism. The filter was placed percutaneously in all cases. While concurrent anticoagulant therapy was utilized where indicated, this amounted to relatively few cases because of the study selection criteria.

Patient Selection and Exclusion Criteria

Patients were selected for this study if they presented with pulmonary embolism, or were at risk for pulmonary embolism from deep venous thrombosis, and anticoagulation was contraindicated, had proven ineffective in the past, or had produced complications. In some patients, the SNF was inserted prophylactically prior to major surgery. It was anticipated that many of the patients enrolled in the study would be in poor general health due to the underlying disorders necessitating insertion of the Simon Nitinol Filter. Male and female patients 18 years old and over were selected for inclusion in the study if they:

1. Had experienced a pulmonary embolism and had a clear contraindication to standard anticoagulation treatment,
2. Continued to have recurrent pulmonary embolism despite anticoagulation treatment,
3. Had massive pulmonary embolism requiring treatment with thrombolytic drugs or pulmonary embolectomy,
4. Were undergoing major surgery with high risk of pulmonary embolism (*e.g.*, hip surgery, major neurological surgery),
5. Had deep venous thrombosis involving the pelvic veins or inferior vena cava and were considered at high risk of pulmonary embolism, or
6. Had experienced pulmonary embolism and were likely to have recurrences because of chronic predisposing diseases such as congestive heart failure, pulmonary emphysema, paraplegia, chronic or recurrent deep venous thrombosis.

Individuals not suffering from any of the above were excluded from this study, along with:

1. Patients with a vena cava shown by venography to be greater than 28 mm in diameter (changed to 24mm after 2 migrations were reported),
2. Patients with acute submassive pulmonary embolism secondary to a transient problem (*i.e.*, sports, injury), or
3. Patients prone to leg edema and skin ulcerations.

Study Population

This report includes all 258 patients who received the Simon Nitinol Filter from February 1988 to November 1990. The data were derived from 23 clinical centers, and the number of patients reported from each center ranges from 1 to 33, with 11 centers contributing 10 or more patients each. Clinical trials were begun at the institutions after approval by their institutional review boards, and appropriate informed consent was obtained from all patients in which the SNF was placed.

Evaluation of Safety and Effectiveness Criteria for Filter Placements over Time

This section will discuss the various complications that have been noted with vena cava filters, in general, and analyze the significance of each. In doing so, complications that affect the safety or effectiveness of any type of vena cava filter are divided into two broad categories. The first category consists of operative complications that occur during the placement procedure. These usually are apparent at the time of the procedure or within 24 hours. The second category consists of postoperative complications. Clinically significant postoperative complications generally occur within one month of placement and almost always within three months (Epstein 1989).

Methods

Insertion procedure. The specific filter placement procedure including cooled saline infusion during the delivery, pre- and post-delivery vena cavography, and post-procedure radiography of the Simon nitinol filter have been described previously (1). Protocol requirements included clinical history and physical examination, recording of the filter insertion and pert-procedural details, and plain radiography of the filter post-procedure and again at 3 and 6 months. The 3 and 6 month clinical examination included history, physical examination of the lower extremities and puncture site, and plain radiography of the filter region. Chest radiography and ventilation perfusion lung scans were optional studies. US imaging of the puncture site and filter region, CT, MR, or digital-subtraction angiography were optional studies performed at the discretion of the principal investigators, generally in symptomatic patients. Laboratory tests of blood and urine for kidney and liver function, and blood clotting were performed. For patients who died during the course of the 6-month study or later, autopsy examination of the vena cava and filter was encouraged, but was not a protocol requirement.

Follow-up studies. Initial and delayed routine follow-up examinations were performed in order to screen for complications at the venipuncture site, such as hemorrhage and venous thrombosis; and at the filter delivery site, including migration, penetration of the vena cava, filter misplacement, tilting or crossing of the filter legs. Recurrent pulmonary embolism was identified by history and physical examination supplemented by nuclear ventilation/perfusion lung scans in suspected cases, according to standard clinical practice. Vena caval occlusion was diagnosed clinically; follow-up imaging by US, contrast-enhanced CT, MRI, or vena cavography was additionally performed in a number of these cases at the discretion of principal investigators. Laboratory tests were obtained to check for any untoward systemic effects of the nitinol material.

Minor complications such as misplacement or tilting were documented in the study records. Major complications were required to be reported to the study monitor within 3 days by telephone and within 10 days in writing. These included filter migrations, recurrent pulmonary embolism, IVC occlusions, and filter-related death. Such major complications were reported during and beyond the 6-month trial period.

Discussion of Safety and Effectiveness Data from the Simon Nitinol Filter Study

Summary

Preexisting conditions for the patients enrolled in the study included many forms of malignancies and cancer, vascular disease, major surgery, and other underlying conditions.

The overwhelming majority of patients (174 patients or 67%) were either in poor or fair health at the time of entry into the study with 16% of the patients having an advanced malignancy. The indications for filter insertion were reported for 245 of 258 and included: contraindication to anticoagulation—158 patients (65%), failure of anticoagulation—33 patients (14%), severe pulmonary hypertension—1 patient (0.4%), surgery—5 patients (2%), trauma—0 patients (0%) and combinations of these 5 categories—48 (19%)

The insertion procedure for the filter was via the femoral approach for 234 (91%) patients, the jugular approach for 15 (6%) patients, and the antecubital approach for 1 (.3%) patient. There were 8 patients (3%) in whom the approach was not noted. Of the 77 patients who died, only one death was related to the filter.

Success of Insertion and Placement

Perforation of the IVC Wall

During the course of caudal migration the diverging legs of the Greenfield filter tend to spread further apart and perforate the vena cava wall (Cimochoski 1980). They may also penetrate adjacent structures such as the aorta, the ureter, or a vertebral body. This process appears to be slowly progressive over a period of months. A protective fibrous tissue sheath develops over the tips of the legs and hooks as a filter extends through the caval wall. Remarkably, perforation of the IVC usually is not associated with symptoms and consequently requires no treatment. The Gunther filter also has shown a high incidence of caudal migration but without further leg spread, since the legs are directed cranially. The Simon Nitinol Filter has shown no perforation of the IVC and minimal caudal migration, probably due to the dual anchoring points of the dome and the filter legs. Filters other than the SNF that have migrated appear to have done so early, prior to three months.

The rate of successful insertion for the Simon Nitinol Filter is 100%. This rate compares quite favorably with the rate of successful insertions for other similar devices, which range from 89 to 99%. There were 10 reports (4%) of difficulties with venipuncture, 18 procedures with reported difficulty advancing the device into the IVC (7%), and 37 reports of difficulty releasing the device into the IVC (14%). As stated, however, none of these difficulties was significant enough to cause a failure of insertion.

With respect to perforation of the vena cava wall and adjacent structures, there have been no reports of such an occurrence with the SNF. There were three (1%) reports of penetration, which is defined as encroachment of the filter legs or dome into the vena cava wall far enough to be visualized via venacavogram. As noted earlier, one of these reports was described as "tenting" and another was indicated as being uncertain. Yet a third report was noted by an investigator but was not substantiated through imaging studies. Penetration itself is not expected to have adverse affects; indeed, for most filters, hooks or barbs in the filter legs must engage the vena cava wall in order to secure the filter attachment.

There was one reported instance of major filter misplacement with the SNF.[1] This problem did not result in any patient safety concerns or in lessening of filter efficacy.

[1] Major misplacement is defined as unintentional placement of the SNF somewhere other than in the intended location, which is in the IVC below the renal vein. Unintended placement in the iliac, hepatic,

Tilting of the filter within the vena cava was included in the investigators' report form simply because it reflects an efficacy criterion for certain other filters. Tilting does not, however, affect the efficiency of the Simon Nitinol Filter as long as the dome remains in contact with the vena cava wall throughout its circumference. There were 54 reports of filter tilting (21%).

Migration of the Device After Insertion

Filter Embolization

The Simon Nitinol Filter is initially secured in the IVC by the outward pressure of its expanding elements and by engagement of the terminal leg hooks with the vena cava wall. Within two weeks the SNF becomes further secured by the formation of a thin neoendothelium which grows over the wires wherever they contact the vein wall. Theoretically, embolization of a filter to the heart or lungs may occur at the time of delivery if its normal expansion is prevented by thrombus forming around it while still in its introducer sheath or if the caval diameter is excessively large. Delayed embolization also may occur within the first two weeks if a filter captures clot, the vena cava pressure rises, and the vena cava consequently becomes overdistended[2] (Greenfield 1977). After two weeks, the points of contact between the device and the vein wall become tightly bound by collagen, muscle fibers, and neoendothelium, and embolization of the filter becomes virtually impossible (Epstein 1989).

Embolization of the filter is a serious complication with variable clinical consequences, comparable to pulmonary thromboembolism. These range from being totally asymptomatic to sudden death. Therapy also ranges from nil to open chest surgery and removal of the device.

Local Filter Migration

It has been noted that vena cava filters may migrate a few centimeters toward the head or toward the feet during the weeks or months following their placement (Sidawy 1986; Miller 1986). This complication is largely dependent upon the specific filter design and reflects the susceptibility of the particular filter to hydrodynamic forces acting upon it. The direction of blood flow and elevated pressure in the vena cava below the filter after clot capture tend to push the filter craniad. Most filters are designed to resist this. A waterhammer effect in the upright position after clot capture, particularly during ambulation, tends to force the filter downward. This may be due principally to the design of those filters. The design of the SNF provides for a second anchor point at the mushroom cap which helps to resist any downward movement. These small migrations usually are clinically insignificant.

The Simon Nitinol Filter is designed to expand to the size of the vena cava and firmly attach to the wall in spite of blood flow or pressure. The ability of the device to remain in position can be assessed by the rate of migration of the filter. During the course of the study, only two instances of migration were noted (0.8%). In one of these cases, the filter was inserted less than two weeks prior to surgery in a patient, with a large vena cava. It is believed that as a result of surgery, the vena cava expanded slightly and the device migrated through the heart to the pulmonary artery. The patient was asymptomatic and experienced no adverse effects as a

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renal vein, or right heart is major misplacement. Placement in the IVC below the renal vein but 1 cm or less too high or 2 cm or less too low is not major misplacement.

[2] The vena cava also may overdistend without clot as a result of right heart failure or during surgical anesthesia involving positive pressure ventilation or abdominal manipulations.

result of the device's migration. Following this incident, labeling for the Simon Nitinol Filter was modified to state that, for filter placement less than two weeks prior to surgery, the maximum vena cava diameter is 24 mm rather than 28 mm as provided in all other situations.

Prevention of Recurrent Pulmonary Embolism

It is clinically recognized that the greatest risk of recurrent pulmonary embolism exists during the first few days or weeks after the development of deep venous thrombosis (DVT) or following the initial pulmonary embolic event. The fresh thrombus may still be undergoing active propagation, is relatively fragile, and is poorly attached to the vein wall. It is during this period that pieces break off most easily and migrate to the lungs. For this reason, anticoagulant therapy is instituted immediately or, if this therapy is contraindicated, a vena cava filter device is inserted on an emergency basis. Within the first few weeks the thrombi become more organized, less fragile, and more adherent so that the recurrence rate falls dramatically (Huisman 1989; Sabiston 1977). Thus, anticoagulant therapy may be discontinued after six weeks, though more commonly it is given for three to six months when the risk of recurrent pulmonary embolism (PE) is minimal. Only if there is an underlying disease that continues to predispose to new episodes of DVT or PE is prophylactic anticoagulant therapy continued for more than six months, possibly for life. Once a filter has been inserted it remains in place and offers protection permanently.

The declining rate of recurrent embolization also is reflected in the incidence of postoperative events. The reported incidence of recurrent pulmonary embolism following placement of a filter is very low, i.e., 1–5% (Epstein 1989; Ricco 1988; Greenfield 1984). Where indicated in the literature, and as shown in the clinical studies for the Simon Nitinol Filter and similar filters, such recurrences almost always occur within the first three months, usually within one month (Epstein 1989). While recurrent emboli may have traversed the filter, they also may originate above the filter or even come from the upper limbs, neck, or right heart (McAuley 1984; Gelsinger 1984). Thus a small PE recurrence rate should be expected even with a theoretical perfect filter.

The intended use of the Simon Nitinol Filter is to prevent large clots from entering the lung and posing a serious threat to the life of a patient. Only emboli that pass through the inferior vena cava are trapped by the filter; it is not intended/designed to filter emboli from other parts of the body. Thus, a certain baseline rate of pulmonary embolism is expected despite filter placement, especially with the treatment of patients with recurrent PE.

There were five reported cases of recurrent pulmonary embolism during the study of the Simon Nitinol Filter, for a rate of 1.9%. Two cases were asymptomatic and three cases were symptomatic; all occurred within approximately one month of filter placement. The first patient, who had a history of pulmonary embolism, had a filter placed on May 2, 1988 prior to neurosurgery. On June 3, 1988, the first symptoms of recurrent pulmonary embolism were noted, along with symptomatic occlusion. One month later, the patient's symptoms were resolving. The second patient, who had a primary CNS malignancy, had fatal symptomatic pulmonary embolism one week after filter placement. Upon autopsy, it was found that the filter was completely occluded. The third patient had a filter placed due to a recent PE. The patient had a brain tumor and had had a brain biopsy two weeks prior to filter placement. During filter placement, it was noted that a partial clot was present above the filter in the right ventricle. Within 36 hours of filter placement the patient had expired from a PE. The fourth patient had a filter placed due to deep vein thrombosis. Although the patient was

asymptomatic, pulmonary emboli were discovered during a routine lung scan two weeks after filter placement. When this patient was followed up two and four months later, no new emboli were found. The fifth patient had a history of pulmonary embolism. The filter was placed on 1/30/89. A routine V/Q scan performed on 3/13/89 demonstrated evidence of a new pulmonary embolus. No symptoms were reported. Of interest was a note on the operative report stating that the filter was placed too low.

Thus, the death rate related to recurrent pulmonary embolism was 0.8%, which compares very favorably with predicate devices. Overall, the Simon Nitinol Filter was shown to be very effective in trapping emboli and preventing embolization to the lungs.

Filter Occlusion

Any vena cava filter is designed to trap emboli in the IVC and thus prevent them from reaching the lung where they could prove fatal. Small or moderate sized emboli trapped in a filter are usually asymptomatic since the residual patency of the vena cava and the normal paravertebral collateral veins permit adequate venous return. A large trapped embolus or a cluster of small emboli may occlude a filter completely and thus block the vena cava. Even this may be asymptomatic if there is a generous network of collateral paravertebral veins. More typically, after a period of days or weeks following filter placement, the occlusion occurs and causes a sudden swelling of both lower limbs. The severity may range from mild swelling at the end of the day to severe swelling even at rest, probably depending upon the state of the collateral veins. In rare extreme cases, the collateral vessels also may be occluded, causing severe painful swelling of both lower limbs. In almost all cases the symptoms of IVC occlusion are transient and resolve almost completely within a few weeks or, possibly, a few months. Treatment is primarily leg elevation, the use of elastic stockings, and, if not contraindicated, use of anticoagulant or thrombolytic drugs. On rare occasions surgical thrombectomy may be required.

In these patients it often is clinically difficult or impossible to distinguish IVC occlusion from extension of the preexisting DVT, since the symptoms may be similar. Any preexisting DVT may be a particular problem because the patients often are unable to receive anticoagulant therapy. In the case of the Simon Nitinol Filter, which is nonferromagnetic, the cause can usually be distinguished by magnetic resonance imaging. In the literature reporting the incidence of occlusion with other filters, and in the results of the present clinical study, occlusions have virtually all occurred within three months of insertion of the filter, generally within two months (Epstein 1989; Greenfield 1984; Kanter 1988; Sfeir 1982). This is in accord with general understanding of the declining frequency of recurrence of pulmonary embolism.

It is probable that occlusions of the SNF are almost always the result of captured emboli, rather than thrombosis in situ, for a number of reasons:

1. The majority of SNF's do not develop thrombi or occlusions.
2. There is usually a delay of days or weeks before occlusions occur.
3. The location of thrombi in the SNF corresponds to sites of trapping rather than regions of maximal wire concentration.
4. Animal and in vitro experiments have shown low thrombogenicity of the nitinol material.

Thus, one can conclude that, for any vena cava filter, occlusion is an expected outcome in a small but significant fraction of patients who experience a major embolic event after filter placement (Simon 1989). It is not a complication in the usual sense of the word, but simply the filter fulfilling its intended purpose (Epstein 1989). In addition, the incidence of filter occlusion likely reflects, primarily, the rate of recurrent embolism in the particular patient population and, secondarily, the mechanical efficiency of the filter. Thus, an inefficient filter might have too low an occlusion rate and too high a pulmonary embolism rate. At the opposite extreme, a filter could have too high an occlusion rate if it could be too easily obstructed by small embolic particles that could be readily managed by the lungs (*e.g.*, the Mobin-Uddin umbrella filter). Optimally, the filter should capture all clinically threatening pulmonary emboli above a critical size. If it is successful, an appropriate rate of IVC occlusion and lower limb venous obstruction is unavoidable.

Studies of vena cava filters typically report on filter occlusion as a complication of filter placement. It is clear, however, that filter occlusion also is indicative of a filter's ability to trap clots effectively and to prevent them from migrating to the lungs (Epstein 1989). Filter occlusion is self-limiting and often resolves spontaneously as the clot is broken down. In other cases, medication may be administered to help dissolve clots.

Of the twenty-five patients for whom filter occlusion was reported, four were asymptomatic and twenty-one were symptomatic. Two of the symptomatic patients also had RPE. In one of these two patients, a complete occlusion and swelling of both legs was observed. One month later, the swelling in one leg had resolved, while the other leg was phlebitic. The patient refused follow-up and was dropped from the study. In the second patient, the patient expired from a PE three days after filter placement. On autopsy, the cava was reported to be completely occluded with clot. Nine other patients with symptomatic occlusion had their symptoms resolved and completed six month follow-up. Five other patients with symptomatic occlusion died of the underlying disease before completing the study and five other patients were lost-to-follow-up. Of the four patients with asymptomatic occlusion, all completed six month follow-up.

The occlusion rate for the Simon Nitinol Filter appears to be slightly higher than the reported rates for certain other devices. As previously discussed, there is a trade-off between occlusion rates and rate of RPE, such that a lower rate of RPE may lead one to expect a higher rate of occlusion, due to more efficient trapping of clots by the filter. The higher rate may also reflect the underlying disease state(s) of our patient population.

Deaths

There were 77 patients who expired during the 6 month study period. In 69 (90%) of these patients, the cause of death was known. In 68 of these patients the death was related to the patient's underlying condition and in 1 additional case the death was associated with the device. In another 8 patients, the cause of death was not specified. The high death rate observed in this study was thought to be primarily related to the patients' poor health status upon entry into the study.

In the one death that was possibly related to the device, the patient had a recent brain biopsy two weeks prior to filter implant. The biopsy confirmed the presence of a brain tumor. The patient developed left lower extremity deep vein thrombosis and was recruited into the study. Filter placement was uneventful except for the fact that the patient had a circumaortic left renal vein and therefore filter placement was anatomically lower because of the caudal position of

the lowest renal vein. The filter was placed approximately 1 cm below the lowest renal vein. The patient had not previously had symptoms suggestive of a PE. Approximately 1 week after filter placement, the patient expired from a PE. On autopsy, there was a large PE in the main pulmonary artery. There was also inferior vena cava thrombus completely occluding the vena cava below the filter and extending past the filter by approximately 2 cm. This fresh inferior vena cava thrombus was anatomically separated from the lower extremity thrombus previously diagnosed. The embolus identified in the pulmonary artery was similar in structure and age to the fresh inferior vena cava thrombus.

Unfortunately, there were no imaging studies performed to confirm if the thrombus formation was new thrombus or an extension of the current thrombus. The investigator summized that extension of the fresh thrombus above the filter could be responsible for the acute PE. Therefore, in the absence of any definitive information relative to this thrombus, a conservative approach was taken to the classification of this PE as possibly related to the lack of the filter's efficiency.

Patient Status

One hundred and twenty patients completed the study, 77 (30%) patients died prior to completing the study and the remaining 60 (23%) patients did not complete the study. Of the 77 patients who expired, 63 (82%) expired early in the study (prior to the 3 month follow-up evaluation). At the 3 month evaluation, 194 patients were thought to be available for follow-up and at the 6 month evaluation, 180 patients were thought to be available. Completion of these two evaluations were 54% and 67% respectively. Of the 60 patients not completing the study, 2 were lost to follow-up, 2 were dropped from the study after refusing further follow-up, 55 did not come back for their final visit and the follow-up data for 1 patient was not recorded.

Discussion

The dome of the filter was noted to tilt less than 25 degrees especially in small venae cavae (1). Tilting is due to the circular dome geometry, which is more easily accommodated in the oval IVC diameter with a short axis less than the dome diameter. Such a mild degree of tilting has been shown in vitro not to affect filtering function since the size of the openings in the dome remain constant (8-9).

Significant proximal migration of Simon nitinol filters was observed in two cases, and each was discovered on routine plain film follow-up. Both patients were asymptomatic, and had no evidence of embolism by nuclear ventilation perfusion scans. One of these patients had an IVC diameter within the upper size range for the filter (28 mm, corrected for magnification) by vena cavography, and had major surgery with positive pressure ventilation, a recognized cause of IVC over-distension a day later (11). For this reason, the manufacturer's recommendation for maximum corrected IVC diameter was lowered for pre-operative cases from 28 mm to 24 mm. A second patient had post-operative placement after orthopedic surgery. In each case, the SNF migrated to the pulmonary artery. Migration probably occurs prior to 2 weeks after filter placement, before the progressive endothelialization develops at the IVC wall contact points and secures the filter hooks and legs (12).

The rates of subacute filter occlusion observed in this series are comparable with reported rates of other filter types (13). However, further comments are warranted in order to explain our observations on the distribution of the patients with symptomatic occlusion, and the four patients with asymptomatic occlusion. In the occlusion group, it is important to note that there was a significantly higher occlusion rate in the first 5 sequentially manufactured lots, compared with the subsequent lots used in the trial. The occlusion rate for lots #1–5 was 15.7%, (22/140), and the occlusion rate for the remaining lots #6-32 was 5.3% (7/133) (Fig.2). The possible explanations of this difference are speculative. Such a three-fold reduction in occlusion rate raises the possibility of a factor in the manufacturing process influencing filter occlusion. For instance, a suboptimum surface finish or material handling process during manufacture could have adversely affected the filter performance initially, and might have been eliminated by subsequent technical refinements (14). An improvement in the methodology of SNF surface treatment was indeed made (15). It is possible that the original surface finish of the SNF was associated with increased thrombogenicity (14). Alternatively, the difference could be related to a change in the patient population characteristics since the initial patients who received the first five lots were predominantly those with advanced malignancy, notably neurosurgical, or other terminal illness cases. Since too many of these sicker patients died before completing the trial, the investigators were requested not to use the filter for patients not expected to survive the follow-up period of at least 6 months. Subsequently, the patients enrolled may have represented a more general population of pulmonary embolism cases. It is our belief that the patient population is the major determinant of the filter occlusion rate, rather than the filter type or inherent thrombogenicity of the metal alloy. Sicker patients will have a higher occlusion rate, particularly if anticoagulant therapy cannot be used.

Conclusion

The study was designed to evaluate the safety and effectiveness of the Simon Nitinol Filter. The device was inserted in patients meeting the inclusion criteria for the study and representing a variety of ages and underlying conditions. The procedures were performed at a number of institutions representative of the settings where the filter is expected to be used. NMT attempted to obtain immediate follow-up for patients experiencing significant complications as well as to follow up patients 3 and 6 months post-implantation.

As an indication of safety and effectiveness, NMT evaluated procedural difficulties and complications, the success of insertion, filter migration, the rate of recurrent pulmonary embolism, and the rate of occlusion. Patient deaths also were tracked and, although the rate was high, only one was possibly due to the lack of filter efficacy. Overall, the data show that the Simon Nitinol Filter is safe and effective.

We recognize that published clinical trials of vena cava filters, including our own, do not meet strict scientific criteria since they are not randomized or comparative trials, involve different patient populations with many confounding clinical variables, employ limited and different imaging procedures due to added patient risk and cost, have different criteria for complications or adverse events, and may involve industrial interests for FDA requirements. Nevertheless, these data are presented as a particular prospective, multicenter clinical experience, recognizing these limitations. It is hoped that a truly randomized, prospective, independent, multicenter comparative clinical trial will eventually be undertaken.

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GLOSSARY OF TERMS

Major Misplacement is defined as the unintentional placement of a Filter not in the intended location immediately below the renal veins, for example, in an iliac, renal, or hepatic vein, or in the right heart. Placement in the IVC below the renal veins, but slightly too high or too low (*e.g.*, 1 cm above or 2 cm below the intended level) is not considered a major misplacement.

Penetration is defined as incursion into the vena cava wall. In contrast, perforation is defined as penetration completely through the vena cava wall.

Migration is defined as any upward or downward movement of the Filter after its placement as documented by follow-up imaging.

Recurrent PE (RPE) is defined on the basis of new perfusion defects on lung scan, filling defects or obstruction, pulmonary arteriogram, or recent thromboembolism at autopsy.

Occlusion, by definition, is the state of being closed. The terms partial and complete occlusion have been used to describe IVC occlusion, either by an embolus captured in the filter or by thrombus propagated from below. Complete occlusions of the IVC are likely to be symptomatic. Occlusions are usually transient due to lysis of the thrombus within weeks or months, or less if thrombolytic drugs are used.

Indication	Patients (n)	Patients (%)
Contraindication to anticoagulation	158/245	64%
Failure of anticoagulation	33/245	13%
Severe pulmonary hypertension	1/245	0.4%
Surgery	5/245	2%
Trauma	0/245	0%
Combinations of the above	48/245	20%
Total reported indications	245/258	95%

Access Anatomy	Patients (n)	Patients (%)
Femoral	234/250	94%
Jugular	15/250	6%
Antecubital	1/250	0.4%
Total reported indications	250/258	97%

Clinical Results	Patients (n)	Patients (%)
Technical success	258/258	100%
Recurrent PE	5/258	1.9%
Symptomatic	3/258	1.2%
Asymptomatic	2/258	0.8%
Death due to recurrent PE†	2/258	0.8%
Migration	2/258	0.8%
Filter Occlusion	25/258	9.7%
Symptomatic	21/258	8.1%
Asymptomatic	4/258	1.6%

† The two deaths represent two of the three symptomatic recurrent PE cases reported here.

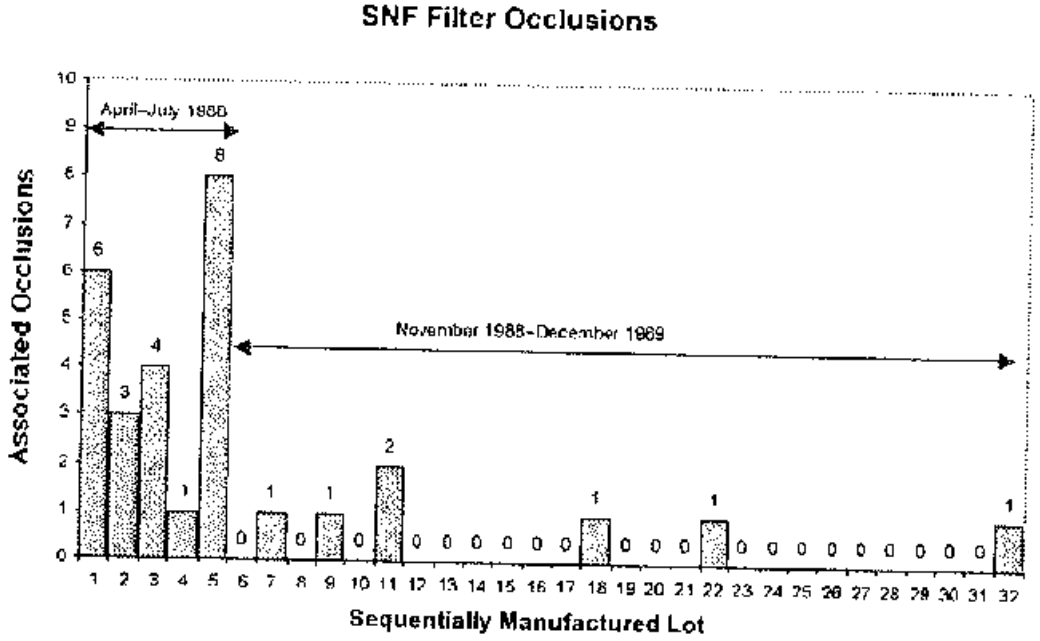

EXHIBIT 2

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN DIEGO, EAST COUNTY REGIONAL CENTER

MARY GIORDANO, individually and on Behalf of the Estate of Jacqueline Keith and other qualified survivors, Plaintiffs, vs. C.R. BARD, INC., a corporation, BARD PERIPHERAL VASCULAR, INC., a corporation, THOMAS BRANNIGAN, M.D., an individual, FRANKLIN KALMAR, M.D., an individual, JULIE LAIDIG, M.D., an individual, SHARP GROSSMONT HOSPITAL, a corporation, SHARP HEALTHCARE, a corporation, and DOES 1 through 100 inclusive, Defendants.	Case No. 37-2011-00069363-CU-PO-EC

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February 5, 2014

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Videotaped Deposition of JOHN McDERMOTT, held at 100 Bayview Circle, Suite 5600, Newport Beach, California, commencing at 10:04 a.m., on the above date, before Kimberly S. Thrall, a Registered Professional Reporter and Certified Shorthand Reporter.

Golkow Technologies, Inc.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

counsel, back on the record. The time is approximately 11:28 a.m.

(McDermott Exhibit 2 was marked.)

MR. LOPEZ: Okay. We'll start marking some documents. Let me find my chart. Okay. Exhibit 2. Exhibit 2 I'm handing to the witness.

Richard, do you want a copy?

MR. NORTH: Yes, I would. Thank you.

MR. LOPEZ: It's -- the title of the document is "Product Performance Specification Recovery Filter and Femoral Delivery System." It has a Bates number at the bottom, which I'm not -- not going to read, just waste time. And then last page there's a date. It says 11/03.

BY MR. LOPEZ:

Q. And my first question to you is whether or not you're familiar -- just generally familiar with a document like this while you were at Bard?

A. Yes.

Q. Okay. And can you describe for a jury what this document -- not -- not the content, but just generally what this document is -- is meant to address?

A. Yeah. It's -- it's called a product performance specification, and it's designed to outline the specifications for the product.

Q. All right. And this is an internal Bard-produced document, correct?

A. Yes.

Q. And would you have been involved with -- somehow with either the review or the contribution to the material -- the material that is found in this document?

A. Generally, no, I wouldn't be directly involved with the preparation of this document.

Q. I mean, it's a 20-some page -- in fact --

A. Seven.

Q. -- it says 1 of 27.

A. Uh-huh.

Q. I mean, it's a -- a document that I would assume that a lot of people contribute to throughout the company, right?

A. Yeah.

Q. You have regulatory --

A. Yes.

Q. -- probably quality, the engineers?

A. R&D. This is a lot of technical detail components, all kinds of little things to make the product.

Q. All right. And then as we go through here, you'll see that there are different, you know, sections

and subsections starting with product identification.

Do you see that?

A. Yes.

Q. As we go through it, it talks about the -- if you look at page 3, it's industry and regulatory reference, industry documents and standards. That means that's -- those are the -- what the company is required to follow with respect to this particular product, correct?

A. Yes. I believe that's what -- that'd be my understanding.

Q. All right. But --

A. Right. Again, I don't build these, but I'm --

Q. I understand.

A. -- generally familiar with it.

Q. And we've generally talked about federal regulations, and I mentioned the Code of Federal Regulations. If you look at page 4, it has the CFR 21 Part 820 with respect to quality system regulations.

Do you see that?

A. Yes.

Q. And then it has -- the next section says "Premarket Notification 510(k)." In other words, these are things that the company knows that as they are dealing with this particular product, that these are the

things that are supposed to guide them through the process to make sure they're -- they're doing things the way they're supposed to be doing them, right?

A. Yes.

Q. And then there's a section on clinical terms. And if you look at page 5 of 5, it has "Intended Use." Do you see that?

A. Yes.

MR. LOPEZ: Jim -- Jim, how can I turn this on? Okay.

BY MR. LOPEZ:

Q. And then the intended use for the Recovery filter was indicated for use in the prevention of recurrent pulmonary embolism via permanent or temporary placement in the vena cava. I'm going to start saying that word right from now on, at least the way the Americans say it. Did I read that correctly?

A. Which word? Vena?

Q. Vena cava. I've been saying cava for a year.

A. Oh, yeah. Cava. Yeah.

MR. NORTH: That's the Italian --

BY MR. LOPEZ:

Q. So that was the intended use of the product?

A. Yes.

Q. According to this document?
A. According to this, yes.
Q. This official Bard document, by the way, right?
A. Yeah. It looks like -- it's got the Bard logo on it, yeah.
Q. "User Needs. The user requires a permanent or temporary filter that can be safely and accurately placed using a femoral vein approach inside the inferior vena cava vein as a preventative measure to patients at the risk of pulmonary embolism."
Did I read that correctly?
A. Yes.
Q. Okay. And then --
MR. LOPEZ: You can go to full screen.
BY MR. LOPEZ:
Q. We're not going to go through this document. It would take another hour. But -- but anyway, it deals with just about every aspect of this particular product, would you agree with me, where it's going to be used and -- like, for example --
A. "Clinical Terms."
Q. -- if we look at page -- page 13 of 27, there's an issue there -- I mean, a section, "Design Input, Other Physical Characteristics." Then you go down to 6.2.1 at the bottom --

MR. LOPEZ: Can you put him up top? Yeah. Thank you.

BY MR. LOPEZ:

Q. -- the Recovery filter under "Design Characteristics," "Filter Clot Capturing Ability," right?

A. Yes.

Q. And the user requirement is -- the user would be the doc- -- the doctor or -- yeah, I guess it could be the patient too?

A. User is usually thought of as the physician implanting the device. He's the one using it.

Q. The "filter must trap blood clots."

Do you see that?

A. Yes.

Q. And do you see here, it says, "Recovery filter clot capturing ability must be equivalent or better than the Greenfield filter"?

There's no equivocation there about that, is there?

A. That's what it says.

Q. Okay. And -- and that would be true if we were to substitute Simon Nitinol filter for Greenfield filter?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. Wouldn't you agree with that?

A. It would be true -- what do you mean?

Q. In other words, that the Recovery filter clot capturing ability must be equivalent or better than the Simon Nitinol filter, wouldn't you agree with that, even though it's not in this document?

A. Oh, you're asking me if I agree --

Q. Yeah.

A. -- with that kind of conceptually outside --

Q. Right. Right.

A. -- of the document?

Q. Right.

A. Well, I would -- I would default to the document.

Q. Okay. All right. Let's look at -- do you see --

A. I don't recall why they chose Greenfield. Maybe because it was market leader. I don't remember, but --

Q. Well, the Greenfield was the predicate device to the Recovery --

A. Okay.

Q. -- I mean, to the Simon Nitinol filter, right?

A. Okay. I -- I guess so. I don't --

Q. So the -- okay. So the Simon --
A. Simon Nitinol was before me.
Q. So the Simon Nitinol -- if the Greenfield filter was the predicate device to the Simon Nitinol filter, then the Simon Nitinol filter under a 510(k) approval process would have to be at least as good or better than the Greenfield filter, right? Well, let me -- let me withdraw that.

I'll represent to you that both the Greenfield filter and the Re- -- and the Simon Nitinol filter were predicate devices. All right?

A. Okay.
Q. And that the representation here that the Recovery filter clot capturing ability must be equivalent or better than the Greenfield filter, do you know, without respect to this document, whether or not that statement would or should apply to the Re- -- to the Simon Nitinol filter as well as to the Greenfield filter? If you don't know, I'll move on to the next question.
A. I don't.
Q. All right. Let's go to the next page.

MR. LOPEZ: And you can move him down now, please.

BY MR. LOPEZ:

Q. And, again, this is page 14 of 17. And this is a continuation of what we just read, and this is the user requirement.

Do you see where I am -- see where I have those hashmarks?

A. Yes.

Q. "Filter must not migrate."

Do you see that?

A. Yes.

Q. "Filter migration resistance. Filter hook strength. Filter must not migrate."

Do you see that?

A. Yes.

Q. "Filter must not perforate the vessel."

Do you see that? This one here.

A. Oh, yeah. Yeah, 6 --

Q. And by the way, user requirement means that these are the expectations --

A. Yeah. This is what --

Q. -- of the doctors?

A. This is what the doctors and the patients -- this is what we all want.

Q. No. This is what they -- their -- their expectations are, right?

MR. NORTH: Objection to the form. No

foundation.
BY MR. LOPEZ:
Q. Well, does user requirement mean that's what the doctors expect and want?
A. That's the requirement that has been established for the design input.
Q. Next, "Filter sleeve, arms and legs must not separate during the lifetime of the device."
Does that mean it -- they shouldn't break?
A. Or come apart.
Q. Or come apart, right?
Skip the next one 'cause -- but we -- it's there for the jury to read if they'd like to.
And then here, "Filter fatigue resistance. The filter must not fracture as a result of corrosives, cyclic stresses within the body."
Do you see that?
A. I see it.
Q. Now, it came to pass that --
MR. LOPEZ: You can turn the screen off.
BY MR. LOPEZ:
Q. -- that once the company started doing some reviews and comparisons between the Recovery filter and other competitive devices, that the Recovery filter did migrate at a higher frequency than competitive products,

MR. LOPEZ: We can't do this all day, Richard.
THE WITNESS: I don't know what -- I'm really trying hard here to --
MR. NORTH: He's asking you to clarify the question --
THE WITNESS: Yeah. I just want to make sure I --
MR. NORTH: -- and you're interrupting him --
MR. LOPEZ: No. He's asking me --
MR. NORTH: -- and you're the one prolonging it.
MR. LOPEZ: He's asking me to change a question. I'm not going to do it.
THE WITNESS: I'm not ask- -- I didn't ask you to change a question. I was just making sure I understood it right, so I was repeating it.
(The following record was read by the reporter:
"Q. My question is whether or not doctors would want to know the information you have, the data that you have in comparing the performance of your device to other devices from the point of efficacy and safety?")
BY MR. LOPEZ:
Q. Can you answer that yes or no?
MR. NORTH: Objection. Asked and answered.

THE WITNESS: Yes, doctors would want to know --

MR. LOPEZ: Thank you.

THE WITNESS: -- the comparison. However, we don't have comparisons 'cause we don't have comparative clinical data, so we have to rely on the literature.

MR. LOPEZ: Move -- move to strike.

BY MR. LOPEZ:

Q. You know that doctors that are using products want to know whatever information exists when a company is looking at its adverse events and whether or not that product at least appears to be more dangerous than other available therapeutic choices that a doctor has? You know that?

MR. NORTH: Objection to the form.

THE WITNESS: I know that they want to see information about adverse events.

BY MR. LOPEZ:

Q. Right. No. What I just asked you. They want to know about comparatives, you know, trending and risk analysis that the company's done based on whatever data that the company has?

MR. NORTH: Objection to the form.

THE WITNESS: Yeah. I -- I -- I can't disagree with that. They would want to know anything and

everything.

BY MR. LOPEZ:

Q. Okay. And you know that some doctors, they only have to hear about one death from a product, whether it be in a case report, whether it be discussions at a meeting, one that could cause them to say I'm not going to use this product anymore until I find out more about it and determine whether or not this is an aberration or whether or not this device is prone to migrate and cause death or to fracture or to have other complications that maybe other products don't have. You know that?

MR. NORTH: Objection to the form.

THE WITNESS: I give doctors more credit than that.

MR. LOPEZ: Well, let me -- let me -- let's make it easier on both of us. Let's see what real doctors really -- how real doctors really react and what real doctors really want to know and what's important to real doctors. Okay?

(McDermott Exhibit 6 was marked.)

BY MR. LOPEZ:

Q. Exhibit No. 6, have you ever seen this document before?

A. I don't know.

MR. NORTH: Objection. Assumes facts not in evidence.

BY MR. LOPEZ:

Q. Do you see that?

A. I see it.

Q. Now, let's look at the next one. "Stopped using, concerned about reported incidents." He didn't say anything about a clinical trial or risk/benefit.

He just -- this doctor is being reported -- another doctor from Missouri is saying he's not going to use this product anymore because of reported incidents, right?

MR. NORTH: Objection to the form.

THE WITNESS: That's what this says.

BY MR. LOPEZ:

Q. And -- and as a -- a person in the medical device field, you know reported incidents is what you would see on a MAUDE database?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. The reported incidents are on a MAUDE database?

A. Yes.

Q. Yeah. Now, I don't know what this is, but I'm -- I'm -- I'd like to find out. Maybe you can help me. I'm going to ask you.

One -- "One of first physicians to receive" blank "memo."

Do you know what blank memo is?

A. I don't.

Q. I'd like to find out why that's -- "But has not used since." He got some memo, and because of that memo, this doctor stopped using the Recovery.

A. Yeah. I don't know --

MR. NORTH: Objection to the form.

THE WITNESS: I don't know what that -- what that refers to.

BY MR. LOPEZ:

Q. Okay. Let's go to the next page. A doctor from Tennessee, $200,000 annual volume doctor. I'm sorry. Texas. 200,000. "Heard of," blank, "migration and won't use." Just heard about a migration, and that influenced the doctor to not use the product.

You would agree with me?

MR. NORTH: Objection to the form.

THE WITNESS: That's what it says.

BY MR. LOPEZ:

Q. I mean, isn't this telling you what's important to doctors as to whether or not they want to use or not use or whether or not the risk/benefit is good for them or not good for them?

MR. NORTH: Objection to the form. No foundation.

THE WITNESS: What it tells me is that the information is important to their decision-making.

BY MR. LOPEZ:

Q. Yeah. One -- this guy heard of a migration and he's -- and he -- just because he heard of it, he won't use it.

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. I mean, we're -- we're getting into the minds of -- of real doctors that are using your product, aren't we, as we go through this --

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. -- as to what's important to them as to whether or not they want to put their patients at risk of using one of your products? Isn't that what this is about?

MR. NORTH: Objection to the form. No foundation.

THE WITNESS: Is that a question?

BY MR. LOPEZ:

Q. Yeah. Isn't that what this is about?

MR. NORTH: Objection to the form.

THE WITNESS: That's what what is about? This

to" -- "the use of the product."

A. I see --

Q. Right here.

A. -- where you're showing, yeah.

Q. All right. I mean, this -- this is a doctor because of a migration issue with your product stopped using it.

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. Don't you think that a doctor like that, before he had any of those experiences would want to know about the experiences that other doctors were having prior to him having those experiences?

MR. NORTH: Objection to the form.

THE WITNESS: Well, you're assuming he's never --

BY MR. LOPEZ:

Q. Wouldn't you -- wouldn't he want to know that? I'm -- it doesn't matter -- I may be wrong about whether he knew or didn't know.

Don't you think that doctors like this would want to know that information?

MR. NORTH: Objection.

THE WITNESS: Yes.

BY MR. LOPEZ:

Q. Okay. Here's a -- here -- here now let's go back to Austin, Texas, a $200,000 account. "Heard of" blank, "migration and won't use."

Just heard of a migration and is not going to use it.

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. Isn't that what this tells us?

A. That's what this says.

Q. Here's an- -- here's someone else that -- an account from Nevada. Maybe that's our doctor, Dr. Phillips -- Mr. Phillips's doctor. "Account has stopped using due to several reported complications."

Okay. Here's someone in California. Do you see where I am? A hundred thousand dollar account. "Has stopped using due to several reported complications." And then right above, "Stopped using due to the migration deaths."

Do you see that?

MR. NORTH: Objection to the form.

THE WITNESS: I do.

BY MR. LOPEZ:

Q. I mean, doesn't that tell you that doctors want to know about whether or not you have a device that's causing more migration deaths than any other device on

the market?

MR. NORTH: Objection.

BY MR. LOPEZ:

Q. Don't you think all of these doctors would want to know that?

A. It sounds like they do know it --

Q. No. But don't you --

A. -- and they're choosing to --

Q. I'm not asking -- you see, we're debating again. You're not -- you're not playing by the rules.

Don't you think every doctor in America would want to know that you are having migration deaths greater than every other device on the market?

MR. NORTH: Objection to the form. This is inappropriate questioning. It's a closing argument.

MR. LOPEZ: What?

THE WITNESS: I'm agreeing with you that doctors want access to as much information as possible.

BY MR. LOPEZ:

Q. But they want to -- okay. Exactly. If -- and if the company has evidence that they're having migration deaths, almost one a month, during the -- the first and second year that a product's on the market many times greater than any other device on the market, don't you think doctors would want to know that?

NEWPORT BEACH, CALIFORNIA, WEDNESDAY, FEBRUARY 5, 2014

2:11 P.M.

THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 2:11 p.m.

(McDermott Exhibit 7 was marked.)

EXAMINATION (RESUMED)

BY MR. LOPEZ:

Q. Okay. I marked an exhibit, Exhibit 7, and I'll describe it, and I'll it put up on the screen. It has a cover e-mail dated June 23, 2008.

I know you weren't there at that -- by then, right?

A. Yeah. I was gone.

Q. And you're not a recipient. I'll -- I'll acknowledge that. And it's a -- the subject matter is "Platinum DIS Discussion."

Do you have any idea what that means, platinum DIS discussion?

A. I am thinking it's another generation filter, but I don't know that for sure.

Q. Okay. I'm going to draw your attention to --

A. Excuse me.

Q. Because we -- we had just talked about this before the break about focus groups and, you know, consultants -- consulting with var- -- and by the way, have you seen this recently as part of your preparation to help refresh your recollection of this document?

A. No.

Q. So we have a -- well, let me show you the document first. That's just the cover e-mail. It's entitled "G3 Vena Cava Design Input Summary." Do you see that?

I think the G3 was a -- a project going on after you left. Is that right, G3? It may have started --

A. I think so.

Q. It may have started --

A. Yeah. It -- it's possible that it was started, but it was definitely subsequent to my --

Q. And then it has a section called "Project Background Information." And then it has a summary of design input. And then -- let's go to page 4 of 17.

MR. LOPEZ: Can you move the witness to the top, Jim, please?

BY MR. LOPEZ:

Q. It says "Multidisciplinary Panel." And then it gives a date here. The reason I'm using it, 'cause it

does reference the time period you were there. It says, "BPV convened a multidisciplinary panel of physicians with a specific expertise and/or interest in thromboembolic disease and IVC filters to discuss filter complications. The panel discussed many issues including expected and threshold rates of various filter complications and possible causes for filter problems."

So we've used this word "expected." I'm not sure we've used "threshold rates" yet. But do you see where I read that?

A. Yes.

Q. It's talking about a multidisciplinary panel in June of 2004. Do you see that?

A. Yes.

Q. And we talked about something that happened in Chicago in 2006.

Does this refresh your recollection that there was a panel that was put together in -- in June of 2004 as well?

A. Yeah. I remember a -- a meeting. I thought it was in Chicago, but I -- I don't -- I'm not exactly sure. I don't -- I don't remember something in 2004. The -- I'm -- it's -- clearly it's happened here, but I can't remember. I don't think they're the same things. Huh? You guys have studied the record. I --

Q. I don't know. I -- there's a lot of documents.
A. Yeah.
Q. With regard --
A. Multidisciplinary leads me to think it's that same session, but I -- I -- I can't remember.
Q. Well, when it says "multidisciplinary," they're talking about different types of doctors or --
A. Yeah. You have different --
Q. -- scientists?
A. Right. Some have guys that may special- -- see more bariatric patients, some trauma surgeons see trauma patients, and, you know, the idea there is you have different physicians with different levels of expertise around different patients that have PE risks.
Q. Right. Okay. So then it -- "With regard to filter migration, the panel's perspective was the following." Bullet point. "It should occur less than 1 percent of the time." Right? "And" -- is that what it says there?
A. Yeah. That's what it says.
Q. "And for prophylactic filter placement, migration of the heart should virtually never happen." Virtually never.
And we know that that never happened, at least in the -- with the documentation you have, about the

Simon Nitinol filter, true?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. That we've seen. Just that one summary. And I mean, I've -- I've got documents that -- documents I can show you, but at least we know in a summary that was done in March of 2004, it said -- stated other devices had migrations except for the Simon Nitinol filter?

A. Of what was reported, yeah.

Q. "The rate should be less than one in a thousand." Right?

A. That's what this says.

Q. Okay. Now, here -- here's a -- an important --

MR. LOPEZ: Could you move the witness down to the -- yeah.

BY MR. LOPEZ:

Q. And as part of that same bullet point, this focus group, these multidisciplinary experts said, "Migration should not be different for retrievable filters than for permanent filters."

I mean, I just want to make sure that we're clear. There's been a lot of discussion about that earlier today and with other witnesses. I mean, the -- the bottom line point here, at least with respect to whoever you were consulting in 2004, that migration

should not be different for retrievable filters than for permanent filters. Did I -- should not, right?

A. That's what it says, yeah.

Q. I mean, it doesn't leave --

A. Yeah.

Q. -- any room for, you know, any con- -- con- -- discussion or wiggle room that migrations can be a little worse with retrievable devices than with permanent devices?

A. That's what -- that's what this says. Certainly, that's the ideal situation, and there's no deb- -- no disputing that. That's what you would definitely shoot for.

Q. And then, "It should be noted, however, that this discussions was mainly" --

DIGITAL VOICE: Ben Cramer has arrived.

BY MR. LOPEZ:

Q. "It should be noted, however, that this discussion was mainly about proximal or cranial migration."

That means towards the heart?

A. Yes. Up, yes.

Q. And then it says, "For caval perforations, the panel believed that symptomatic perforations should be less than 1 percent and the rate of asymptomatic

perforations does not matter."

That's the panel. I'm -- I'm -- that's what the panel said?

A. That's what this document says the panel said.

Q. And, by the way, the panel is -- is giving input -- like you said earlier, you know, you said we went out and got input and advice from clinicians. And this is part of that?

A. Yeah. I'm assuming that's -- I mean, I'm just looking at this report. I don't know which doctors were there, but that's -- yeah, that's what it says.

Q. All right. "In summary, the multidisciplinary panel felt the following about general filter performance."

Do you see where I am? I just underlined that.

A. Yes.

Q. "A retrievable filter is expected to perform just as well as a permanent filter." Right?

A. That's what it says.

Q. And, again, it doesn't leave room for, you know, anything other than the fact that that's what you were getting from the clinicians. They expected performance from a permanent filter -- from a retrievable filter the same as you would get from a permanent filter, right?

A. Yes. That's what they want.
Q. And their other expectation is a filter should not migrate no matter what the size of thrombus burden it captures, right?
A. That's what they want, yes --
Q. According --
A. -- according to this, yeah.
Q. Do you know if that ever -- that type of advice from clinicians ever changed about these expectations?
A. I doubt it. I mean, I think we would all -- all the physicians and all the device people would like to set the bar in that place, yeah.
Q. And, by the way, it says "expected."
A. Yes. Yep.
Q. Clearly says "expected."
A. Yeah.
Q. All right. So that was in two thousand and -- this was in 2008, this document. But is it fairly clear that they're discussing a focus group about what happened in two thousand -- in June of 2004 when -- when -- we talked about some of this, when I think by then you had three migration deaths, right?
MR. NORTH: Objection to the form.
BY MR. LOPEZ:
Q. From the Recovery filter?

snickers when I used the word --

MR. NORTH: He did not snicker.

MR. LOPEZ: Well, it's on the video record.

THE WITNESS: No, I did. I had a reaction --

MR. LOPEZ: Yeah. There you go.

THE WITNESS: -- because I just --

MR. LOPEZ: Thank you.

THE WITNESS: -- find the -- I'm just having trouble tracking the question.

BY MR. LOPEZ:

Q. If you can't answer it because of the way it's phrased, I will move on to the next question. How's that?

A. Yeah. That's fine.

Q. Good.

A. Why don't we move on.

Q. And I think we agreed earlier that patients have to have relevant and -- information that the company has about not only the good stuff about the product, but the -- the potential bad information about the product in order for the patient and the physician to have a reasonable and appropriate and informed consent about even to use the product, right?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. That's a no-brainer?

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. Wouldn't you agree?

A. Well, what I would agree is that the companies with the devices certainly have an obligation to provide all the relevant information for the doctors to make their product choices.

Q. Okay. Again, I -- I think it's -- you've -- you've not answered my question.

A. Really?

Q. I'm going to ask --

A. I think I --

Q. I'm going to ask Kim to answer it again because I didn't ask what the -- you know, I just asked whether or not it's important. Listen -- listen to the question and -- and then you can judge yourself.

THE COURT REPORTER: The question is: "I think we agreed earlier that patients have to have relevant in-" -- "relevant information that the company has about not only the good stuff about the problems about" -- "about the potential bad information about the products in order for the patients and the physicians to have a reasonable and appropriate and informed consent about even to use the product, right?"

"Q. I mean, that is what you do, you monitor the MAUDE database, to see if there is some sort -- a certain trend into the future with respect to migrations, fractures, perforations that might unnecessarily be exposing somebody to a likely --")

THE COURT REPORTER: Excuse me. I have a snafu.

MR. LOPEZ: I can do it over. I can start over.

THE COURT REPORTER: Sure.

BY MR. LOPEZ:

Q. The reason that the MAUDE database is monitored is because you want to see if you're seeing any signals or trends as to what may be happening -- what could happen in the -- if you continue to market a device, right?

A. Yeah. I think -- I think --

Q. Is that one of the reasons?

A. Yeah. You monitor events.

Q. Right. And -- and the reason you do that is because if -- if you're starting to get evidence that this thing is more dangerous than other potential alternative therapies for this patient population, you want to be able to tell doctors that they ought to know

about these increased risks so they can actually include in their differential other types of therapy that may not be -- may not have these risks?

MR. NORTH: Objection to the form.

THE WITNESS: Yeah. I mean, the physician communication is always, you know, important and one of the considerations for monitoring the complaint rates.

BY MR. LOPEZ:

Q. I mean, didn't you -- your company, and at least with respect to the Recovery filter, start to get a -- a pretty strong clue and signal that the longer you kept the Recovery mark- -- device on the market, the more people's lives were going to put at risk of migration deaths and even fracture -- fracture -- embolizations from fractures?

Didn't you -- didn't you come to that conclusion as you were evaluating all of this and --

MR. NORTH: Objection to the form.

BY MR. LOPEZ:

Q. -- maybe you got a -- and maybe there's a problem you ought to be sharing with patients and doctors about that device so that they can do what some of these priority people did and say I'm not using it anymore; I'm going to do something else?

MR. NORTH: Objection to the form.

THE WITNESS: Is that one question or two? It was a long one. I just want make sure I --

BY MR. LOPEZ:

Q. Well, which one do you -- I mean, I --

A. I don't know. They're tough -- when you string them together like that, they're kind of tough to keep track of. I'm not trying to be difficult, but it sounds like a statement, and then it turns into a question, and so it's hard to track it.

Q. Okay. So you're confused about what I'm asking with respect to --

A. Well, just --

Q. If -- if you are, I'll -- I'll ask it again.

A. Yeah. Why don't we do that. That's good.

Q. Have you -- don't you think as you were getting these fairly consistent reports of migratory deaths with the product, that -- that doctors might want to know the details about that so that they can factor that into their deliberative process when they're considering whether to use your device, somebody else's device or choosing some other therapeutic avenue for their patients?

MR. NORTH: Objection to the form.

THE WITNESS: Yeah. I think doctors want access to information to make good clinical choices.

an adverse event, you can provide it, but you have to redact the name of the doctor and the reporting person and the patient, right?

A. That's the legal understanding.

Q. I mean, you know that, too, as the president of the company?

A. Actually, I -- I -- I didn't know that until today.

Q. Oh, okay. You should -- you should send out a memo when you get back to your office about that.

MR. NORTH: Objection to the form.

MR. LOPEZ: I'm just teasing. Relax.

BY MR. LOPEZ:

Q. Okay. I think I spent enough time on that, but -- but the bottom line is we -- we don't know. I mean, so the -- so anoth- -- another way that the -- the risk of adverse events could be much higher than what we may be seeing on some of these charts is if some of these serious adverse events don't even make their way into the files of Bard or into the files of FDA?

A. Yeah. There's a risk of underreporting.

Q. Right.

A. The company is pretty diligent, though. This was an area that we put considerable effort into. Yeah. I was there.

Q. How closely did you monitor that?
A. Closely.
Q. Who monitored --
A. We monitored complaints every month.
Q. Who -- who was it -- oh, you did monitor complaints every month?
A. Sure.
Q. So you knew -- you knew what was going on every month about what was being reported to the company about the Recovery and the G2 filter while you were there?
A. Yes.
Q. And you saw the trending as you were there?
A. Yes.
Q. You knew it was going up and up and up and up and up, right?
MR. NORTH: Objection to the form.
THE WITNESS: We saw the numbers.
BY MR. LOPEZ:
Q. And you saw the numbers continue to rise at a fairly steady rate, right?
MR. NORTH: Objection to the form.
THE WITNESS: Saw the -- saw the rate increasing.
BY MR. LOPEZ:
Q. You saw the deaths continuing to mount, right?

MR. NORTH: Objection to the form.
THE WITNESS: I had access to the reports.
BY MR. LOPEZ:
Q. And you saw the migration -- reports of migrations continue to mount over that period of time?
A. I -- I -- I think I said yes to that.
Q. And you saw fractures continuing to mount month after month after month, right?
MR. NORTH: Objection to the form.
THE WITNESS: I saw the complications.
BY MR. LOPEZ:
Q. And I even showed you a document that showed that as time went on, not only did the numbers increase, the -- the percentage of those type of complications increased. I just showed you a document that shows that.
A. I don't remember which document you're referring to, but . . .
Q. And by the way, did your sales continue to go up during that period of time?
A. On what products?
Q. On the Recovery and the G2 filter --
MR. NORTH: Objection to the form.
BY MR. LOPEZ:
Q. -- as these numbers continued to mount.

A. Right, but I thought it was -- I thought it was. Again, I'm testing my memory a little bit here; it's been, you know, a long time -- that there were kind of expected rates or complication rates of vena cava filters, and that the Recovery fell within those expected rates. That's my recollection.

Q. All right. The -- but, again -- I -- I know I'm harping over and over and over again on this issue, and Mr. North is shaking his head yes, I am, because I -- the -- the -- it -- it's important from the perspective of my clients and who I represent and the doctors who were involved in this process to fully understand the messaging that was getting out to them from the company.

Do you understand that?

A. I understand what you're saying.

Q. And you understand that the comp- -- it's the company's obligation to get information to the doctors about the -- the -- the benefits and the risks and the complications and the trending of adverse events out to physicians. Nobody else has that --

DIGITAL VOICE: Alan Graves has left the conference.

BY MR. LOPEZ:

Q. No one else has that obligation.

EXHIBIT 3

Product: Recovery Filter and Femoral Delivery System

PPS Number: PPS070016 **Revision Number:** 0

1.0 Product Identification

The ***Recovery*** Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the ***Recovery*** Filter provide excellent filtering efficiency and allow percutaneous placement through standard 7 French I.D. angiographic introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the ***Recovery*** Filter to be deployed with the filter tip centered and prevents the legs from crossing. The ***Recovery*** Filter is designed to act as a permanent filter. When clinically indicated, the ***Recovery*** Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The ***Recovery*** Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional Removal Procedure for specific removal instructions).

MRI Compatible: The ***Recovery*** Filter implant is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

2.0 Scope

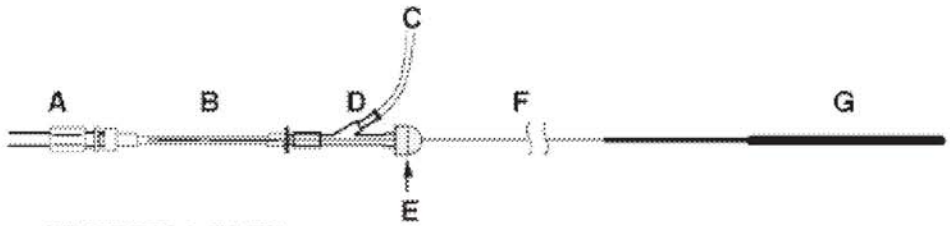
This document will cover clinical, environmental, physical, material, shelf life, mechanical, biological, radiopacity, chemical, sterilization, packaging, labeling, and equipment interface characteristics of the Recovery Filter and Femoral Delivery System with respect to verification and validation testing activities.

3.0 General Product Description

The Recovery Filter System consists of the Filter and Delivery System. The Recovery Filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. These twelve wire form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The Recovery Filter is intended to be used in vena cava with diameters up to 28 mm.

The Recovery Filter Delivery System is illustrated in Figure A. The Delivery System consists of a 7 French I.D. introducer sheath and dilator, the Recovery Filter, a storage tube with a saline infusion port, and a pusher system. The Recovery Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery Filter System



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

The Recovery Filter may be used as a permanent filter or be implanted temporarily to treat a temporary risk of pulmonary embolism. The Recovery Filter system is packaged in kits. Kit A consists of the 7 Fr. Teflon introducer catheter set. Kit B consists of the delivery system including the Recovery vena cava filter preloaded in a storage tube, connected with a Touhy-Borst Y-adapter, and nitinol pusher wire assembly. Kit A and Kit B are packaged in a unit pouch. The system is packaged in a femoral delivery configuration. The filter systems are manufactured, packaged, labeled, and sterilized, ready for distribution. The Recovery Filter system is intended for disposable, one time use.

4.0 Industry and Regulatory Reference

4.1 Industry Documents and Standards

Document Number	Title
Not Applicable	American College of Radiology (ACR) Standard for the Performance of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism (2000)
ASTM D-903:1998	Standard Test Method for Peel or Stripping Strength of Adhesive Bonds
ASTM D4169-01:2001	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4728-01:2001	Standard Test for Random Vibration Testing of Shipping Containers
ASTM D5276-98:1998	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM F640-79:2000	Standard Test Methods for Radiopacity of Plastics for Medical Use
EN 550:1994	Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
EN 868-1:1997	Packaging Materials and Systems for Medical Devices Which are to be Sterilized – Part 1: General Requirements and Test Methods
EN 868-2:1999	Packaging Materials and Systems for Medical Devices Which are to be Sterilized – Part 2: Sterilization Wrap – Requirements and Test Methods
EN 12006-3:1999	Non-Active Surgical Implants – Particular Requirements for Cardiac and Vascular Implants – Part 3: Endovascular Devices
EN 46001:1996	Quality Systems – Medical Devices – Particular Requirements for the Application of EN ISO 9001
ISO 594-1:1986	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part1: General Requirements
ISO 594-2:1998	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
ISO 9001:1994	Quality Management Systems - Requirements
ISO 10555-1:1995(E)	Sterile, Single-Use Intravascular Catheters – Part 1 : General Requirements
ISO 10993-1:1997	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
ISO 11135:1994	Medical Devices – Validation and Routine Control of Ethylene Oxide

4.1 Industry Documents and Standards	
Document Number	Title
	Sterilization
ISO 11607:1997	Packaging for Terminally Sterilized Medical Devices
ISO 13485:1996	Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001
4.2 Regulatory Documents and Standards	
Document Number	Title
FOD#24	Guidance for Cardiovascular Intravascular Filter 510(k) Submission (1999)
CFR 21 Part 820 (4-1-02 Edition)	Quality System Regulation
FDA 95-4158:1995	Premarket Notification 510(k): Regulatory Requirements for Medical Devices

5.0 Clinical and Environmental Terms

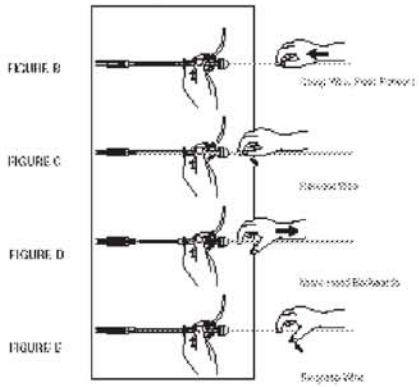
Note: Intended Uses and User Needs are subject to design validation

5.1 Clinical Terms			
Term	***Design Input***	***Design Output***	
	Description / Statement	**Pass or Fail**	**Reference Document(s)**
Intended Use	The Recovery Filter is indicated for use in the prevention of recurrent pulmonary embolism via permanent or temporary placement in the vena cava.	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
User Needs	The user requires a permanent or temporary filter that can be safely and accurately placed using a femoral vein approach inside the inferior vena cava vein as a preventative measure to patients at risk of pulmonary embolism.	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
Term	**Description / Statement**		
Patient population inclusion/exclusion criteria	•Pulmonary thromboembolism when anticoagulants are contraindicated. •Failure of anticoagulant therapy in thromboembolic disease. •Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced. •Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. •Temporary risk for pulmonary embolism.		
Known Warnings, Contraindications or Precautions	•Patients with inferior vena cava (IVC) diameters greater than 28 mm. •Pregnant patients where fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully. •Patients with risk of septic embolism.		

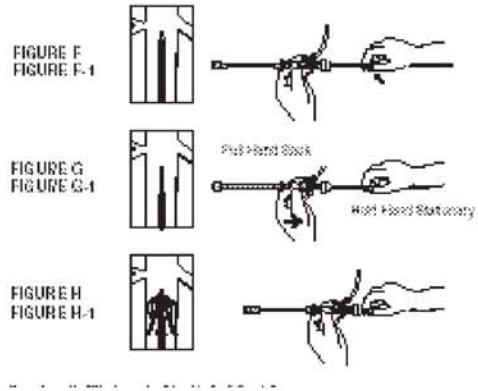
5.1 Clinical Terms

Term	*Design Input*	*Design Output*	
	Description / Statement	**Pass or Fail**	**Reference Document(s)**
Clinical procedure	Insertion of the 7 French Introducer Catheter and Preliminary Venography 1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis. 2. Prep, drape and anesthetize the skin puncture site in standard fashion. 3. Select and open the filter package. Open Kit A Introducer Catheter package. 4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle. 5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein. **NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.** 6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein. **NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.** 7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency. **NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.** 8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement		

5.1 Clinical Terms

Term	*Design Input*	*Design Output*	
	Description / Statement	**Pass or Fail**	**Reference Document(s)**
	9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion the introducer catheter tip should be 1 cm below the lowest renal vein. 10. Remove the filter and delivery system from Kit B. 11. Connect a 500-mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer and measure the IVC diameter, correcting for magnification (typically 20 percent). Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely. **NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.** 12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction. *Advancement of Filter, Illustrated*  		

5.1 Clinical Terms

Term	*Design Input*	*Design Output*	
	Description / Statement	**Pass or Fail**	**Reference Document(s)**
	13. Advance the Filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the Filter with each forward motion of the pusher wire (Figures B-E). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement. 14. Continue forward movement of the pusher wire until the Filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter. **Filter Release/Deployment** 15. Deliver and release filter as described below: Figure F: Firmly hold the pusher wire handle. Figure F-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC. **NOTE: Do not deliver the Filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary Filter by withdrawing the introducer catheter as described below.** ***Filter Release, Illustrated*** 		

5.1 Clinical Terms			
Term	*Design Input*	*Design Output*	
	Description / Statement	Pass or Fail	Reference Document(s)
	Now release the Filter by unsheathing it in the IVC as follows: **Position the Filter tip 1 cm below the lowest renal vein.** **Figure G: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.** Figure G-1: Unsheathing of Filter in IVC. Figure H: The position of the hands at the completion of the unsheathing process. Figure H-1: The Filter deployed in the IVC. 16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and delivery catheter assembly and pulling back on the pusher wire. 17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency. **Follow-up Venacavogram** 18. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s). 19. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.		
Medical specialties of user	Interventional radiologists, vascular surgeons, interventional cardiologists and other trained medical professionals.		

5.2 Environmental Terms	
Term	Description/Statement
Use environment	This device will be used in Angiography Suites, Intensive Care Units and Cardiac Catheterization Labs.
Environmental / safety consideration	Distribution: The device function and package integrity must withstand cyclical shipping and storage temperatures and humidity conditions encountered worldwide. Otherwise, specific conditions must be noted.

5.2 Environmental Terms	
Term	**Description/Statement**
	During Use: The device must be capable of cycling between typical room conditions and the body's internal environment. Also, imaging equipment will expose the device to radiation.

6.0 Engineering Terms

6.1 Physical Characteristics:

6.1.1 Dimensional Characteristics					
	Design Characteristic	***Design Input***		***Design Output***	
		User Requirement	**Engineering Specification**	**Pass Or Fail**	**Reference Document(s)**
6.1.1.1 Recovery Filter					
6.1.1.1.1	Filter Weld Bead Diameter	The arms and legs must be welded to the sleeve properly.	Bead diameter must be 0.072" +0.003" /-.002".	Pass	SA4676200-3
6.1.1.1.2	Filter Weld Bead Height	The arms and legs must be welded to the sleeve properly.	Bead height must be 0.170" +0.020/ -0.010	Pass	SA4676200-3
6.1.1.1.3	Overall Filter Height	The overall height dimension of the filter is not to exceed 1.97".	1.621" ± 0.005"	Pass	SA4676200-1
6.1.1.1.4	Filter Arm Diameter	The arm diameter must not exceed 1.34".	1.102" - 1.299"	Pass	SA4676200-1
6.1.1.1.5	Filter Leg Diameter	The leg diameter is not to exceed 1.38".	1.181" – 1.339".	Pass	SA4676200-1
6.1.1.1.6	Filter Compression Profile	The filter is deliverable through a 9 Fr ID introducer sheath.	0.085" +0.002'/-0.000"	Pass	RD-RPT-095, RD-RPT-088
6.1.1.2 Recovery Filter Delivery System					

6.1.1 Dimensional Characteristics

	Design Characteristic	Design Input		Design Output	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.1.1.2.1	Introducer Sheath OD	Maximum System OD must be 15 Fr.	0.118" ± 0.002"	Pass	RM4674901
6.1.1.2.2	Dilator ID	The dilator must be 0.038" Guidewire compatible.	0.041" ± 0.002"/-0.001"	Pass	RM4675040, RD-RPT-095
6.1.1.2.3	Introducer Sheath Length	Introducer sheath length needs to be approximately 48 cm.	20.04" ± 0.15"	Pass	RM4674901
6.1.1.2.6	Pusher Wire Effective Length	All filters must deploy when Y-body is retracted to the position where the PEBAX portion of the handle is bottomed out against the Touhy-Borst, not the silicone valve.	Length of Distal End of PEBAX Portion of the Handle to the Distal End of the Pusher Pad is 78.5 ± 0.63 cm.	Pass	ETR-03-07-07

6.1.2 Key Materials

	Design Characteristic	Design Input		Design Output	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.1.2.1 Recovery Filter					
6.1.2.1.1	Filter	Filter must recover at body temperature. Must be biocompatible and EtO sterilizable.	Nitinol, Alloy Type 508, -5 C< Af<15 C	Pass	SA676200
6.1.2.2 Recovery Filter Delivery System					

6.1.2 Key Materials

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.1.2.2.1	Handle	Must be biocompatible and EtO sterilizable.	304 SS, ¾ full hard, ASTM A 269 (hypotube) PEBAX 4033 (handle)	Pass	RM0213514
6.1.2.2.2	Pusher Wire	Must be biocompatible and EtO sterilizable.	Nitinol, Alloy Type SE-508, Af <10 deg C	Pass	RM0315006
6.1.2.2.3	Catheter	Must be biocompatible and EtO sterilizable.	FEP (Teflon) White 8-10% Barium (extrusion) Polyethylene white (hub)	Pass	RM4674901
6.1.2.2.4	Dilator	Must be biocompatible and EtO sterilizable.	FEP, lt. Blue 8-10%% Barium (extrusion) Polyethylene white (hub)	Pass	RM4675040
6.1.2.2.5	Introducer Marker Band	Must be biocompatible, EtO sterilizable and must be radiopaque	Platinum/Iridium (90/10)	Pass	RM0267039

6.1.3 Other Physical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.1.3 Recovery Filter and Recovery Delivery System					
6.1.3.1	Shelf Life	The device must have a minimum shelf life of 3 years.	3-year expiration dating	Pass	STR-02-09-01
6.1.3.2	Filter Weld Joint Visual Inspection	The arms and legs must be welded to the sleeve properly.	No discoloration except light yellow can be present on the welds.	Pass	RD-RPT-092

6.1.3 Other Physical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.1.3.3	Filter Weld Bead Physical Attribute	The arms and legs must be welded to the sleeve properly.	The weld must totally cover the upper surface of the sleeve.	Pass	RD-RPT-092
6.1.3.4	Filter Tip Radiopacity	Filter tip must be radiopaque.	Visible under fluoroscopy	Pass	RD-RPT-088
6.1.3.5	Filter Radiopacity	Filter must be radiopaque.	Visible under fluoroscopy	Pass	RD-RPT-088
6.1.3.6	Introducer Sheath Surface Finish	The effective length of the introducer sheath must be free from extraneous matter.	Upon visual inspection, the introducer sheath must be free of extraneous matter (reference ISO 10555-1:1995(E)).	Pass	PQ.14.500.443, PQ.14.500.444, QC-0321
6.1.3.7	Introducer Marker Band Radiopacity	Marker bands must be radiopaque.	Visible under fluoroscopy	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121

6.2 Mechanical Characteristics:

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.1 Recovery Filter					
6.2.1.1	Filter Clot Capturing Ability	Filter must trap blood clots.	Recovery filter clot capturing ability must be equivalent or better than the Greenfield filter.	Pass	RD-RPT-103

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.1.2	Filter Migration Resistance	Filter must not migrate.	Filter must resist migration at 50mm Hg when fully occluded in diameters up to 28 mm.	Pass	RD-RPT-100, RD-RPT-088
6.2.1.3	Filter Hook Strength	Filter must not migrate.	≥70 gf	Pass	RD-RPT-101, RD-RPT-104
6.2.1.4	Filter Radial Strength	Filter must not perforate the vessel.	Recovery filter radial strength must be equivalent or less than the SNF.	Pass	RD-RPT-102
6.2.1.5	Filter Weld Strength/Integrity	Filter sleeve, arms, and legs must not separate during the lifetime of the device.	≥ 5 lbf.	Pass	RD-RPT-092
6.2.1.6	Filter Hook Creep	The filter must not be permanently deformed as a result of being constrained in the storage tube for a period of time.	There must be no increasing trend in creep.	Pass	RD-RPT-089
6.2.1.7	Filter Fatigue Resistance	The filter must not fracture as a result of corrosives or cyclic stresses within the body.	There must be no fractures of filter elements (arms or legs) due to the cycling of an equivalence of 10 years of pulmonary output (32 million cycles) in a corrosive environment.	Pass	RD-RPT-099

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.1.8	Filter IVC Diameter Range	One Size Filter fits into Vena Cava Diameters of ≥15 mm and ≤28 mm	The filter must center and withstand a minimum of 50 mmHg pressure drop in simulated IVC's of 15 mm and 28 mm diameter.	Pass	RD-RPT-100 (pressure drop) and RD-RPT-095 (centering)
6.2.1.9	Filter Centering	The filter must self-center within the inferior vena cava.	The filter sleeve must be at a minimum distancing of 1/3 the diameter form the vessel wall.	Pass	RD-RPT-095, RPT-100, RPT-088, RPT-118
6.2.2 Recovery Filter Delivery System – Introducer Sheath and Dilator Requirements					
6.2.2.1	Kink Resistance	Sheath and Introducer should resist kinking and crushing.	Sheath and Introducer must resist kinking and crushing.	Pass	RD-RPT-095
6.2.2.2	Side port and Flushing Capabilities	The system must have side port/flushing capabilities.	The system must have side port/flushing capabilities.	Pass	RM0085, SA4676200, RD-RPT-095
6.2.2.3	Dilator Removal	The dilator must be able to be removed safely with minimal force.	The dilator must be able to be removed safely with minimal force.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.2.4	Introducer Sheath and Y-body/Storage Tube Connection	The introducer sheath hub and Y-body/storage tube must be able to be connected with minimal force.	The introducer sheath hub and Y-body/storage tube must be able to be connected with minimal force.	Pass	RD-RPT-095
6.2.2.5	Leading Edge of Dilator/Sheath	The leading edge of the dilator and sheath shall be tapered and smooth.	The leading edge of the dilator and sheath shall be tapered and smooth.	Pass	RM4675040, RM4674901

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.2.6	Introducer Sheath Tensile Strength	The introducer sheath tensile strength should exceed what the system will be exposed to during use before breaking.	≥ 5 lbf.	Pass	RD-RPT-015 (SNF Design Dossier)
6.2.2.7	Dilator/Sheath Hub Strength	Minimum hub strength for dilator and sheath is 5 lb.	≥ 5 lbf.	Pass	ETR-02-11-01
6.2.2.8	Introducer Sheath Retraction	Introducer sheath must be able to be removed safely.	Introducer sheath must be able to be removed safely.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.3 Recovery Filter Delivery System – Pusher Wire Requirements					
6.2.3.1	Kink Resistance	The pusher rod must resist kinking and crushing.	The pusher rod must resist kinking and crushing.	Pass	RD-RPT-088, RD-RPT-095, RD-RPT-118
6.2.3.2	Spline & Sheath Proximal Band Alignment	The pusher wire must have the ability to align the distal/proximal location of the filter with the delivery sheath.	The pusher wire must have the ability to align the distal/proximal location of the filter with the delivery sheath.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.3.3	Filter Advancement	Pusher wire and filter advancement must be sufficiently controllable so as to avoid unintentional deployment of the filter.	Pusher wire and filter advancement must be sufficiently controllable so as to avoid unintentional deployment of the filter.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.3.5	Pusher Wire Radiopacity	The pusher pad and spline must have acceptable radiopacity near the distal end.	The pusher pad and spline must have acceptable radiopacity near the distal end.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.3.6	Pusher Pad Tensile Strength	Pusher pad must have a pull strength exceeding what the system will be exposed to during use before breaking from the wire.	≥ 3 lbf.	Pass	RD-RPT-093, STR-02-09-01
6.2.3.7	Spline and Pusher Wire Joint Tensile Strength	Pusher wire and spline joint must have a tensile strength exceeding what the system will be exposed to during use before breaking from the wire.	≥ 3 lbf.	Pass	RD-RPT-093
6.2.3.8	Proximal Cylinder Stop and Pusher Wire Joint Tensile Strength	Pusher wire and proximal cylinder stop joint must have a tensile strength exceeding what the system will be exposed to during use before breaking from the wire.	≥ 3 lbf.	Pass	ETR-03-07-04
6.2.3.9	Pusher Wire Handle Joint Pull Strength	Pusher wire and handle joint must have a tensile strength exceeding what the system will be exposed to during use before separating from the wire.	≥ 5 lbf.	Pass	RD-RPT-093
6.2.3.10	Pusher Wire Tensile Strength	Pusher wire must withstand a certain amount of force without breaking.	≥ 5 lbf. (0.0130" diameter wire)	Pass	RD-RPT-091, RD-RPT-094

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.4 Recovery Filter Delivery System – System Requirements					
6.2.4.1	Filter Deployment Accuracy	The physician must be able to accurately deploy the filter.	± 1 cm	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121, RD-RPT-115
6.2.4.2	Deployment Force	The physician must be able to deploy the filter with minimal force.	The physician must be able to deploy the filter with minimal force.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.4.3	Filter Advancement into Introducer Sheath	The physician must be able to advance the filter from the storage tube into the introducer sheath with minimal force.	The physician must be able to advance the filter from the storage tube into the introducer sheath with minimal force.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.4.4	Filter Advancement Through Introducer Sheath and RO Bands	The physician must be able to advance the filter through the introducer sheath and RO bands.	The physician must be able to advance the filter through the introducer sheath and RO bands.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.2.4.5	Filter Deployment	The filter deployment must be simple, requiring minimal end-user manipulation.	The filter deployment must be simple, requiring minimal end-user manipulation.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121, RD-RPT-115
6.2.4.6	Delivery of Filter through the Femoral Vein	The filter delivery system must be capable of deploying the RNF filter in caval geometries bounded by the indications for use (i.e. delivered into the IVC via the Femoral vein).	The filter delivery system must be capable of deploying the RNF filter in caval geometries bounded by the indications for use (i.e. delivered into the IVC via the Femoral vein).	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121, RD-RPT-115

6.2 Mechanical Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.2.4.7	Filter Recoverability	The filter delivery system must be capable of deploying the RNF filter such that the filter sleeve would be accessible.	The filter delivery system must be capable of deploying the RNF filter such that the filter sleeve would be accessible..	Pass	RD-RPT-095, RD-RPT-115
6.2.4.8	Touhy-Borst Nut Tightness	Physician must be able to open the Touhy-Borst nut.	Physician must be able to open the Touhy-Borst nut.	Pass	ETR-03-10-13
6.2.4.9	Filter Hook and Spline Interaction	Filter hooks must not dislodge from the spline during normal shipping or storage.	Filter hooks must not dislodge from the spline during normal shipping or storage.	Pass	ETR-03-10-13

6.3 Fluidic Characteristics

6.3 Fluidic Characteristics

	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.3.1	Not Applicable	None	None	N/A	None

6.4 Electrical, Electronic and Radiation Characteristics

6.4 Electrical, Electronic and Radiation Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.4.1	MRI Compatibility	Filter must be MRI compatible.	Filter must be MRI compatible.	Pass	ETR 02-12-01

6.5 Thermal Characteristics

6.5 Thermal Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.5.1	Not Applicable	None	None	None	None

6.6 Chemical Characteristics

6.6 Chemical Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.6.1	0.9% Saline Solution Compatibility	Delivery system must be compatible with a 0.9% saline solution.	Delivery system must be compatible with a 0.9% saline solution.	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121
6.6.2	Contrast Compatibility	Delivery system must be compatible with contrast.	Delivery system must be compatible with contrast.	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121

6.7 Biological Characteristics

6.7 Biological Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.7.1	Biocompatibility	The product must be biocompatible.	ISO 10993-1:1997	Pass	RD-RPT-088, RD-RPT-019, RD-RPT-025, NAMSA Report #99T-1580-00 (TI264-500, TI251-800, TI261-300, TI261-301, MG074-100, TU010-807)

6.8 Sterilization Characteristics

6.8 Sterilization Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.8.1	Sterility	The entire product must be sterile.	The entire product must be tested for sterility following EtO sterilization (reference EN 550:1994and ISO 11135:1994).	Pass	STR-02-09-01, ETR-02-11-01, 0321938-4 (Covington), E03-019 Product Adoption Evaluation – Covington)
6.8.2	Number of Exposures	The delivery system must be able to be sterilized a minimum of two cycles.	2X EtO	Pass	STR-02-09-01, ETR-02-11-01, 0321938-4 (Covington), E03-019 Product Adoption Evaluation – Covington)

6.9 Operating Environment

6.9 Operating Environment					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
Transport and Storage					
6.9.1	Warehouse Environment	Product must survive warehouse environment intact.	Product must be functional after being subjected to warehouse environmental conditions (reference ASTM D4169-01:2001, ASTM D4728-01:2001, and ASTM D5276-98:1998).	Pass	RFS-2481 (same as SNF)
6.9.2	Truck / Air Transport	Product must survive transport intact and undamaged.	Product must be functional after being transported (reference ASTM D4169-01:2001, ASTM D4728-01:2001, and ASTM D5276-98:1998).	Pass	RFS-2481 (same as SNF), ETR-03-10-13
Product Use					
6.9.3	Angiography Suite, ICU or Cath. Lab	Product must be able to be used under normal conditions in an angiography suite or ICU environment.	Product must be able to be used under normal conditions in an angiography suite or ICU environment.	Pass	RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121

6.10 Human Factors and Ergonomic Characteristics

6.10 Human Factors and Ergonomic Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.10.1	Not Applicable	None	None	None	None

6.11 Packaging Characteristics

6.11 Packaging Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.11.1	Product Sterility	Packaging must allow and maintain sterility of the product.	Packaging must allow and maintain sterility of the product.	Pass	STR-02-09-01, ETR-02-11-01, 0321938-4 (Covington), E03-019 Product Adoption Evaluation – Covington)
6.11.2	Pouch Seal Peel Strength	The seal must remain intact to maintain product sterility.	≥ 0.75 lb/in.	Pass	RFS-2481 (same as SNF), PV-PG-500 RNF (Glens Falls)
6.11.3	Pouch Seal Visual Integrity	The seal must remain intact to maintain product sterility, no voids should be present.	The seal must remain intact to maintain product sterility, no voids should be present.	Pass	RFS-2481 (same as SNF), PV-PG-500 RNF (Glens Falls)

6.12 Labeling Characteristics

6.12 Labeling Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.12.1	Label Requirements	Identifies part number, part description, use before date, and lot number.	Bard Corporate labeling and format requirements.	Pass	Labels (PK5022912, PK5022911, PK50229018, PK5019531)
6.12.2	Instructions for Use Requirements (IFU)	Clear and accurate directions explaining safe and effective medical device use must be provided to the user.	Bard Corporate IFU requirements.	Pass	IFU (PK5014853)

6.13 Equipment Interface

6.13 Equipment Interface					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.13.1	Dilator Hub, Introducer Hub, and Y-Body Side Port Equipment Interaction	Dilator hub, introducer hub, and Y-body side port must properly interface with a standard saline drip system, syringe, and power injector.	Standard female luer fitting, and standard female luer fitting on Y-body.	Pass	RD-RPT-095, RD-RPT-088, RD-RPT-118, RD-RPT-119, RD-RPT-121

6.14 Aesthetic Characteristics

6.14 Aesthetic Characteristics					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.14.1	Not Applicable	None	None	None	None

6.15 Environmental/Disposal Considerations

6.15 Environmental/Disposal Considerations					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
6.15.1	Product Hazardous Waste Disposal	Potential biohazard following use.	The following warning should be present in the IFU: “After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations."	Pass	IFU (PK5014853)

7.0 Marketing Terms

7.0 Marketing Terms					
	Design Characteristic	*Design Input*		*Design Output*	
		User Requirement	Engineering Specification	Pass Or Fail	Reference Document(s)
7.1	Accurate Placement	The delivery system must be able to accurately deploy the filter to the intended target location.	Reference sections 6.2.1., 6.2.2., 6.2.4	Pass	Reference sections 6.2.1., 6.2.2., 6.2.4
7.2	Flexibility	The introducer/dilator and delivery system assembly must track through the venous system without kinking.	Reference sections 6.2.1., 6.2.2., 6.2.4	Pass	Reference sections 6.2.1., 6.2.2., 6.2.4
7.3	Low Profile	The user requires a delivery system with a low profile.	Reference sections 6.2.1., 6.2.2., 6.2.4	Pass	Reference sections 6.2.1., 6.2.2., 6.2.4
7.4	Self-Centering	The filter must self-center.	Reference sections 6.2.1., 6.2.2., 6.2.4	Pass	Reference sections 6.2.1., 6.2.2., 6.2.4

8.0 Regulatory Terms

8.1 FDA Guidance Documents	
Document Number	Title
CFR 21 Part 820 (4-1-02 Edition)	Quality System Regulation
8.2 Other Regulatory Considerations (USA or International)	
Document Number	Title
Not Applicable	Not Applicable

9.0 Revision History

Revision Number	Date	CR Number	Description
0	11/03	BPT 7081 [6]	Conversion of NMT/Creation of BPV PPS for Recovery Filter and Femoral Delivery System/ L. Jaramillo

EXHIBIT 4

From: Ciavarella, David [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=DCIAVARELLA]
Date: 12/27/2005 2:33:22 PM
To: Barry, Brian [Brian.Barry@crbard.com], Ganser, Christopher [Christopher.Ganser@crbard.com]
Subject: FW: G2 Caudal Migrations

My comments to Cindi and Gin.

_____

From: Ciavarella, David
Sent: Friday, December 23, 2005 2:32 PM
To: Walcott, Cindi
Cc: Allen, Shari; Schulz, Gin
Subject: RE: G2 Caudal Migrations

Thank you Cindi.

I think we should discuss these further so I can get a better understanding of each one. But first, it would help if I had a little more information.

From what you've sent me, it seems to me that the biggest (worst case) consequence of these migrations is that they are accompanied in a majority of cases by tilting. This raises the concern of lack of efficacy, that is, are the filters now in place to perform clot interruption? I would guess not in several of these cases at least.

I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, mis-deployment and maybe one or two additional things. Can you tell me the total number of complaints (not damaged packages and the like) and total number of units distributed?

How many MDRs have we had for G2?

The G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2? Can you also send me the total complaints rate and MDR complaint rate for SNF?

I'll be in the office next Tues and Wed; maybe we can talk one of those days.

David

_____

From: Walcott, Cindi
Sent: Tue 12/20/2005 6:14 PM
To: Ciavarella, David
Cc: Allen, Shari; Schulz, Gin
Subject: G2 Caudal Migrations

David,

During a conference call with the design team of the G2 filter and Chris Ganser today, the caudal migrations of the G2 were briefly discussed.

Chris asked if I had submitted any MDRs on these events yet and I answered yes. Chris asked me to review the events with you to determine what events have the potential for serious injury and establish a baseline for the future. Presently, based on the description of the events and the history of a filter being removed, I have coded them all as reportable. Please note that I cut the descriptions straight out of what was entered into Trackwise. I can see that some of the descriptions are a bit rough.

Please see the attachment, which has a description of the events to date.

1. Record 63855- I submitted that one as an MDR because there was also a report of perforation with this patient. Perforations have caused serious injuries with previous filters. We have always reported perforations of the Recovery Filter and the Simon Nitinol filters. The doctor also removed the filter due to the perforation and migration.
2. Record 65220- I submitted this one as an MDR, as the filter migrated into the renal veins and caused the patient flank pain.
3. Record 65851- I reported this one as it migrated 3cm and is currently at the iliac confluence.

Thanks for your assistance,

Cindi

EXHIBIT 6

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

----------x

IN RE BARD IVC)

FILTERS PRODUCTS) No. MD-15-02641-PHX-DGC

LIABILITY LITIGATION)

----------x

DO NOT DISCLOSE - SUBJECT TO FURTHER

CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF DONNA-BEA TILLMAN, Ph.D.

WASHINGTON, D.C.

FRIDAY, AUGUST 4, 2017

9:18 A.M.

Reported by: Leslie A. Todd

where there were very short-term excursions and pressure that went above 50 millimeters of mercury, but I don't think the quality of that data or that information is necessarily enough to say that 50 millimeters was not the appropriate value to use at that time.

Q It could have been much higher, though, right, based on that data?

MR. ROGERS: Object to the form.

THE WITNESS: My -- my expectation based on the -- some of the animal work that I did during my graduate work is that a lot of times things happen when you're doing animal studies. You get glitches or short excursions of data that may not mean anything. And based on the limited information we have about what actually happened during those animal studies, it's hard for me to say that that's enough information to say that the 50 is not an appropriate number to use.

BY MR. LOPEZ:

Q Was that -- were those animal studies provided to FDA?

A I don't believe that that data is of the quality that it's relevant to be provided to FDA

A It's my understanding that the purpose of those guidelines has changed somewhat since the original publication in 2003.

MR. LOPEZ: Move to strike, nonresponsive.

BY MR. LOPEZ:

Q Have you read Dr. Grassi -- Grassi's deposition testimony about that?

A I have not reviewed Dr. Grassi's deposition.

Q Okay. Have you read Dr. Anne Roberts' deposition about Bard's use of SIR guidelines?

A I have not reviewed Dr. Roberts' deposition.

Q Okay. Do you know who Dr. Roberts is?

A I am aware of who she is.

Q Did -- was she -- did she work at FDA at any time while you were there?

A So it's my understanding that she did a fellowship at FDA, and I'm not exactly sure to what extent our time overlapped.

Q Then how is it that you know who Dr. Anne Roberts is?

A Because I saw references to her in

something I read relatively recently.

Q Did you read her report that she did in collaboration with Dr. Tom Kinney and Dr. Sanjeeva Kalva?

A No, I did not.

Q That was not provided to you?

A I am not aware of that report.

Q And you are not even aware it exists?

A No, I shouldn't say that. I am aware it exists because counsel discussed it with me briefly yesterday, so I know it exists, but I haven't seen it or reviewed it.

Q You just knew -- you just found out about it yesterday?

A Yes, I just found out about it recently.

MR. LOPEZ: Okay. Can I have a copy of that report?

BY MR. LOPEZ:

Q So is Dr. Roberts one of the authors of the SIR guidelines that we've been talking about?

A I don't know who all the contributing authors were on the guidelines.

Q Have you ever talked to any of the authors of those guidelines?

filter being challenged by a clot and moving to someone's heart and causing death?

MR. ROGERS: Object to the form and foundation.

THE WITNESS: I'm not aware of Dr. Kinney's opinions.

BY MR. LOPEZ:

Q Well, didn't Bard represent to FDA that a lot of the things they were telling FDA were as a result of consulting with their medical consultants?

A You'd have to show me a particular representation to FDA that you're talking about.

Q If FDA wanted to know what the acceptable rate of death was from a filter not staying where it was put when it got challenged by a clot and causing death, and Bard knew that its consultants were telling them that the acceptability of that happening is zero, shouldn't Bard have told FDA that?

A Can you repeat the question?

Q If FDA wanted to know what the acceptable rate of death was from a filter not staying where it was put when being challenged by

a clot and causing death, and Bard knew that its consultants were telling them that the acceptability of that happening is zero, shouldn't Bard have told FDA that?

MR. ROGERS: Object to the form.

THE WITNESS: You started off by saying if FDA had wanted to know. So if FDA had wanted to know, they would have asked. And if Bard had information that said that it -- the acceptability was that it would be zero, then I would have expected them to share that with FDA, if FDA had asked them that question.

BY MR. LOPEZ:

Q How many deaths were reported in the 2003 SIR -- I'm going to start saying SIR because I do SRI all the time and mess that up. So if I say "SIR guidelines," you'll know I'm talking about S-I-R?

A Okay.

Q Okay. How many deaths that were referenced in the SIR guidelines of 2003 were deaths caused by a device being challenged by a clot and embolizing to a patient's heart and causing death?

THE WITNESS: So I think you have to be careful when you talk about design defects.

BY MR. LOPEZ:

Q Well, let's put it this way -- let me put it this way. I'll withdraw the question.

The only way for a warning to deal with a design deficiency is for the warning to say: We have a design deficiency. Wouldn't you agree?

MR. ROGERS: Object to the form.

BY MR. LOPEZ:

Q That's the warning.

A I think that you -- you have to be careful about making those generalizations. When you do a risk analysis, you look at a device. Let's say you identify a potential risk to health. Then the best thing to do is to design the device to address it, to fix it.

So I would agree that if you have a risk, the best thing is to redesign it. If you can't design it, you provide a work --

THE REPORTER: Excuse me. Can you please --

THE WITNESS: Oh, I'm sorry. I know I'm doing it again. I'm sorry. All right. Let me

start --

BY MR. LOPEZ:

Q Step back. Just slow down.

A I'm hungry.

So when you design a device, and you have a risk, ideally the best thing to do to mitigate a risk is to design around it. You design the device so the risk goes away.

Q Right.

A If you can't do that, then you can implement some kind of way to protect the person against the risk. You put in a barrier or a guard so you can't touch the heart -- the hot part.

Finally, if you can't do either one of those things, you label around it. You say, There's a risk here. We can't -- it's a risk we have to accept, but we're going to label around it.

So, I mean, that's standard design considerations.

Q I'm going -- I'm going to hire you just for that part of your testimony. Is that okay? Can I do that?

MR. LOPEZ: I'm just kidding. Let's

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re Bard IVC Filters)

Products Liability Litigation)

----------) No. MD-15-02641-PHX-DGC

Do Not Disclose -

Subject to Further Confidentiality Review

This is the videotaped deposition of MURRAY R. ASCH, M.D., taken before Terry Wood, CSR, RPR, a court reporter, at Victoria Room, Residence Inn, 160 Consumers Drive, Whitby, Ontario, Canada, on the 2nd of May, 2016, at 9:13 a.m..

Reported by: Terry Wood, CSR (Ont.), RPR

Videographer: Jim Lopez

will be noted on the stenographic record. Counsel, also here in person will be noted on the stenographic record. The court reporter is Terry Wood, and she will now swear in the witness.

MURRAY R. ASCH, M.D., AFFIRMED;

EXAMINATION BY MR. BOATMAN:

Q. Good morning, Dr. Asch.

A. Good morning.

Q. Would you please state your full name for the record?

A. My full name is Murray Ross Asch.

Q. And are you a medical doctor?

A. Yes, I am.

Q. Dr. Asch, we're here today to discuss the work you did for Bard from 1999 to about 2004. Can you please tell the jury what you did for Bard?

A. I was involved in a pilot study to assess the safety and feasibility of retrieving a new -- a newly designed IVC filter.

Q. And Dr. Asch, before we get into that study, I'd like to ask you just a few questions about yourself. First, what kind of doctor are you?

A. I'm an interventional radiologist.

time the study was done, I was working at a university-associated hospital. And I needed to submit to my local hospital review ethics board.

Q. And did you obtain the necessary approvals?

A. Yes, I did.

Q. Did anyone at Bard or NMT ever tell you the purpose of the study was so that Bard could get FDA clearance for the filter?

MR. NORTH: Objection to the form.

THE DEPONENT: That was never told to me.

BY MR. BOATMAN:

Q. If Bard had told you that getting FDA clearance was the purpose of the study, would you have agreed to do the study?

A. I would have designed the study in a different way.

Q. Did anybody at Bard ever tell you how your study fit into the filter approval process?

A. The plan that was communicated to me was I was going to do a pilot study to help open the doors for a large multi-center American study, which would then be utilized to obtain FDA approval.

Q. This is a get-the-ball-rolling study?

A. Yes.

MR. NORTH: Objection to the form.

BY MR. BOATMAN:

Q. How did Bard describe this initial pilot study to you?

A. Exactly as that, as an initial feasibility study, safety study, let's get the ball rolling, let's see if this device will perform in humans as it has in animals and in the lab. And then once we know that it's safe, it will then be easier to obtain approval for a real - a bigger study in the United States.

Q. Are there ethical rules that govern studies like the one Bard asked you to conduct in this case?

A. Yes. There are very strict ethical rules that govern all studies.

Q. Does a doctor working with a medical device company expect the company to be honest and transparent in working with you?

A. I absolutely expect that.

Q. Do you expect the company

retrieve the IVC filter without resultant damage to the inferior vena cava.

Q. And what -- how successful, how did the study turn out as far as retrievability?

A. It was very successful. We were able to retrieve virtually all of the filters that we attempted to retrieve.

Q. Were there complications with the filters you experienced in the study that were independent of the retrievability aspect of the study?

A. Yes, there were complications related to the IVC filter.

Q. What were those complications?

A. There was a filter migration, and one of the patients experienced filter fractures.

Q. Did you also have a problem with the splines twisting?

A. Yes. Early on in the study there was a problem with deployment as a result of the insertion device, including splines twisting.

Q. And let's talk about the splines twisting first. When did that happen in the study?

A. That happened early on.

Q. Okay. And can you tell us what the

A. Yes, I expressed those concerns.

Q. Did Bard do a root-cause analysis to try to determine the cause of the filter fracture in patient 33?

A. Yes, they did.

Q. Did Bard -- did you get a copy of that root-cause analysis?

A. I don't -- I don't recall receiving a written root-cause analysis, but I do recall conversations with them.

Q. And I know there were several people you were dealing with, but can you tell us primarily who you were dealing with when you say you had these conversations?

A. The main people -- the main person I dealt was with Rob Carr because he was at NMT. He was the engineer. He was most intimately involved in the study.

Q. Did Bard determine the cause of the two fractures in patient 33?

MR. NORTH: Objection to the form.

THE DEPONENT: What was communicated to me was that there was potential weakness at the site of the weld, and there was potential for increasing the

robustness, if you will, of the device by manufacturing it with larger diameter metal.

BY MR. BOATMAN:

Q. Did Bard tell you they were going to change the design or manufacturing process to try to prevent future filter fractures?

MR. NORTH: Objection to the form.

THE DEPONENT: That is my recollection.

BY MR. BOATMAN:

Q. And who told you that?

A. I believe it was Rob Carr.

Q. Did you trust Bard to have conducted a proper root-cause analysis as to the cause of the fractures in patient 33?

A. Yes, I expected that.

Q. And did you trust Bard to make the changes to the filter to prevent future fractures that they told you they were going to make?

A. Yes, they had already made changes based on the first spline problem we had. So I assumed they would make changes based on this problem as well.

Q. Did anyone at Bard ever tell you that Kay Fuller had expressed concerns internally at Bard, that Bard had not done a proper root-cause

MR. BOATMAN: Objection. Beyond the scope of direct.

THE DEPONENT: I am aware that caval perforation is a common complication of a variety of filters, but the essential thing to consider is that there is a big difference between a complication or a perceived complication we see at the time of an imaging study and a complication that subsequently goes on to kill a patient. There are -- at a quick glance in this article, I don't see any reference to any adverse events other than an imaging abnormality. No one died and no unusual procedures had to be performed.

BY MR. NORTH:

Q. Doctor, did I understand your testimony earlier in response to some of Mr. Lopez' questions to be that you do not believe Bard should have sought FDA clearance for the Recovery filter or begin selling the device commercially until it conducted a more robust study than the one you performed?

A. Yes. That is what I believe and that is what Bard had led me to believe at the time they contacted me and asked me to be involved in this study.

EXHIBIT 12

Radiology

Murray R. Asch, MD, FRCPC

Index terms:
Embolism, pulmonary, 60.72
Venae cavae, filters, 982.1267
Venae cavae, interventional procedures, 982.1267

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Radiology 2002; 225:835–844

Abbreviations:
DVT = deep venous thrombosis
IVC = inferior vena cava
PE = pulmonary embolism

[1]From the Department of Medical Imaging, Mount Sinai Hospital/University Health Network, 600 University Ave, Suite 564, Toronto, Ontario, Canada M5G 1X5. From the 2001 RSNA scientific assembly. Received November 14, 2001; revision requested January 29, 2002; revision received March 12; accepted June 26. Supported in part by NMT Medical and C. R. Bard. **Address correspondence to** the author (e-mail: *masch@mtsinai.on.ca*).

Author contribution:
Guarantor of integrity of entire study, M.R.A.

Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter[1]

PURPOSE: To evaluate preliminary clinical experience in humans with the Recovery nitinol filter (RNF) for the inferior vena cava, especially the efficacy of the device and safety of its retrieval.

MATERIALS AND METHODS: Thirty-two patients were followed up to assess for filter efficacy and for ability to remove the filter.

RESULTS: Sixteen men and 16 women aged 18–83 years (mean, 53 years) underwent treatment with the RNF. Indications for placement were recent pulmonary embolism ($n = 16$), recent deep venous thrombosis ($n = 20$), and/or prophylaxis ($n = 2$). Four patients had contraindications to anticoagulant therapy, and four had complications from anticoagulant therapy. The filter was successfully placed in 32 patients. In 24 (100%) of 24 patients, the filter was successfully retrieved with a jugular approach. The mean implantation period was 53 days (range, 5–134 days). Trapped thrombus was seen within the filter in seven cases. In one patient with a large trapped thrombus, the filter was noted to have migrated 4 cm cephalad. There were no episodes of pulmonary embolism or insertion-site thrombosis.

CONCLUSION: This preliminary experience in humans confirms the efficacy of the RNF. It also demonstrates the feasibility and safety of retrieval up to 134 days after implantation.

Anticoagulation is the accepted standard therapy in patients with venous thromboembolic disease. When contraindications to anticoagulant therapy are present, interruption of the inferior vena cava (IVC) can be performed to prevent the passage of large life-threatening emboli to the lungs. With the introduction of the Greenfield filter in 1973, placement of IVC filters has become accepted as the most common treatment alternative (1). Since the advent of devices that can be placed percutaneously, the number of filters inserted on a yearly basis has increased markedly (2,3). It has been specifically noted that there has been an increase in the implantation rate in young patients (2). Coincidentally, follow-up studies have revealed a 2%–19% incidence of late complications, often arising many years after filter placement (4,5). As the prevalence of patients with IVC filters has increased, so too have reports of guide wire entrapment with subsequent displacement of filters to the heart (6,7). Concerns about the long-term safety of IVC filters have resulted in the suggestion that permanent filters be avoided, especially in patients with a long life expectancy (8).

In many patients, the period of risk from anticoagulant therapy is relatively short. Other than the treatment of patients with widespread malignancy, there are few clinical situations that require placement of a lifelong IVC filter. Several studies have revealed that up to 30% of patients receive anticoagulant therapy following placement of an IVC filter (4,9). Decousus et al (10) demonstrated a reduction in the incidence of pulmonary embolism (PE) in patients with filters compared with patients treated with anticoagulant therapy at the 12-day mark, and no difference in outcome between patients with filters and those treated with standard anticoagulant therapy at 2 years. These researchers also observed an increased risk of recurrent deep venous thrombosis (DVT) in the patients treated with filter placement compared with those treated with anticoagulants alone (10). These data support the use of nonpermanent IVC filters.

There are two varieties of nonpermanent filters—temporary and retrievable. Temporary filters are attached to some form of tether, such as a guide wire or catheter, and thus must be removed (11). The anchoring mechanism of temporary filters often results in some degree of patient immobility and may also serve as a nidus for infection. If filter thrombosis occurs, a new, permanent filter must be placed. Retrievable filters may be left in place permanently or they may be retrieved, depending on what is appropriate for each individual clinical situation. Currently, the only retrievable device approved for use in Canada is the Gunther Tulip filter (Cook Canada, Stouffville, Ontario) (12,13). In their review of data from a multicenter registry, Lorch et al (14) state that filters that can be retrieved or left in place at the option of the physician would be an appropriate kind of temporary filter to use as long as the retrieval procedure was technically easy and had a low complication rate.

Although there are many differences between temporary and retrievable filters, all currently approved devices share a common limitation—length of residence prior to removal. Current instructions for use for most nonpermanent filters state that the filter must be removed within 10–14 days of placement. The predominant concern is the development of endothelialization, which would make subsequent removal impossible. Endothelialization has been shown to lead to explantation problems after as short a period as 12 days (15).

The Recovery nitinol filter (RNF) (NMT Medical, Boston, Mass), a retrievable IVC filter, is a new device (Fig 1). It is composed of 12 0.13-inch nitinol wires that extend from a nitinol sleeve. It has six arms and six legs. The resting diameter of each of the arms is 30.5 mm; the resting diameter of each of the legs is 32 mm. The filter measures 4 cm in height. It has undergone benchtop and animal testing since 1998. On the basis of the evidence that the filter is safe, effective, and retrievable up to 22 weeks after insertion, the purpose of this study was to evaluate our preliminary clinical experience with the efficacy of this filter and the safety of its retrieval in humans.

MATERIALS AND METHODS

Patients and Filter Insertion

Thirty-four consecutive patients who required an IVC filter and who were anticipated to return to anticoagulant therapy 10 days to 12 weeks after the procedure or to not require anticoagulant therapy for 10 days to 12 weeks were selected to receive an RNF between April 2000 and November 2001. Patients were considered for placement of this filter only if their estimated life expectancy was greater than 2 years. Retrieval was planned for all patients. The device was released for use on a special-access basis by the Health Protection Branch of the federal government of Canada, in Ottawa, Ontario, and its use was approved by the University of Toronto ethics department and by the institutional review board. Informed consent was obtained from all patients. Specifically, the option of placement of a permanent filter or an approved removable filter such as the Gunther Tulip retrievable filter (Cook Canada) was offered.

The filters were placed at multiple sites of a multiinstitutional medical imaging department by a single staff vascular and interventional radiologist (M.R.A.). The timing of filter removal was coordinated with the referring physician and/or with special referral to a hematologist. The decision regarding return to anticoagulant therapy was usually made by the referring physician on the basis of his or her assessment of the risk of bleeding versus concern regarding propagation of lower-extremity DVT. All 32 patients who received filters (two patients were found to have anatomic conditions unfavorable for filter placement) had the decision to return to anticoagulant therapy made for them in this fashion. In cases in which it was deemed that filter removal had to be postponed beyond 12 weeks for a medical indication, specific approval from both the ethics department and the Health Protection Branch was sought and granted.

All procedures were performed with standard sterile technique. Conscious sedation was achieved with midazolam (Versed; Sabex, Boucherville, Quebec, Canada) and fentanyl citrate (Sublimaze; Faulding, Dorval, Quebec, Canada), which were simultaneously administered at the patient's request. All devices were placed via the femoral vein on the side contralateral to the side of venous thrombosis, if present. Access was obtained with real-time ultrasonographic (US) control and a 19-gauge single-wall puncture needle (Cook Canada) after local anesthetic with 1% xylocaine (Lidocaine; AstraZeneca, Mississauga, Ontario, Canada) had been applied to the puncture site. A 5-F pigtail catheter (Cook Canada) was subsequently advanced over a 0.035-inch standard J-tip guide wire (Cook Canada), and digital subtraction angiography of the IVC was performed in frontal and lateral projections with hand injection only. The IVC was measured in both planes with a ruler, a dime, or a calibrated catheter and was assessed for duplication and thrombosis. The number and position of the renal veins were also noted. Selective renal vein catheterization was not performed. The filter was not placed if the corrected diameter of the vena cava exceeded 28 mm.

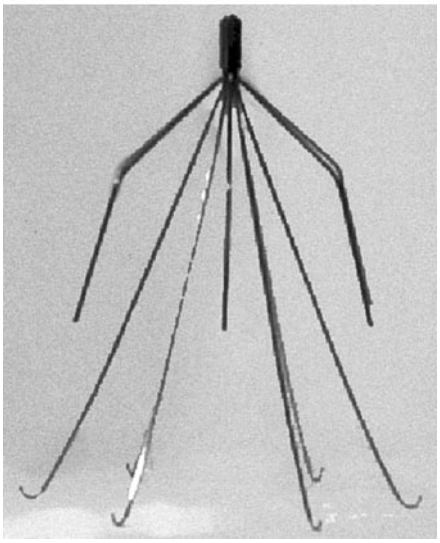


Figure 1. RNF retrievable IVC filter. (Original magnification, ×3.) The device is manufactured from nitinol wire of 0.013 inch in diameter. It is 4 cm in height, and the base can accommodate a vena cava up to 28 mm in diameter. There is dual-level filtration from both the arms and the legs.

In a single instance, the filter was placed by means of a portable C arm in the intensive care unit as a result of concern that this ventilated patient could not tolerate transfer to the interventional suite. In this case, right-sided access was impossible because of the presence of a previously unsuspected iliac venous thrombosis. There was an indwelling left femoral venous line, so a new, separate left femoral puncture was performed. This patient was already undergoing prophylactic broad-spectrum antibiotic therapy for his underlying condition, and he did not subsequently develop signs of sepsis secondary to the procedure.

Following placement of the 6-F introducer sheath, the filter was advanced and deployed with a technique similar to that used with the Simon nitinol filter (NMT Medical). The sheath and filter reservoirs were primed with a standard heparin and saline flush prior to placement. Neither a

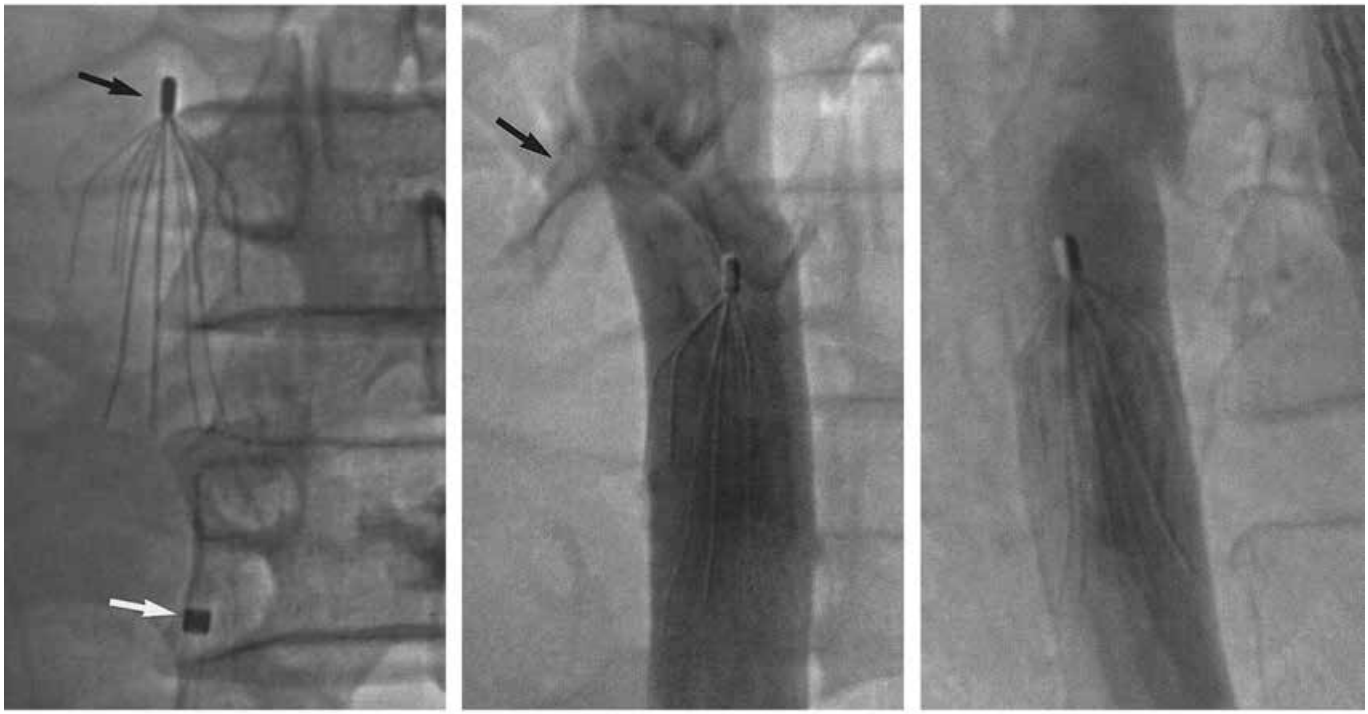


Figure 2. Vena cavograms depict filter placement. **(a)** Frontal scout view obtained just before the postinsertion vena cavogram shows the highly visible nitinol RNF filter with its tip at the L1-2 interspace (black arrow). Note the radiopaque marker band on the tip of the insertion sheath (white arrow). **(b)** Frontal postinsertion vena cavogram demonstrates that the filter is aligned with the caval axis, with its tip approximately 1 cm caudal to the right renal vein (arrow). **(c)** Lateral vena cavogram demonstrates alignment in this plane as well.

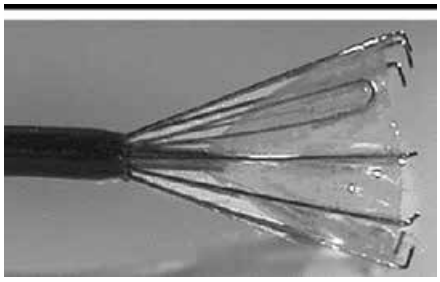


Figure 3. Retrieval cone, which is constructed with nine metal claws covered by a urethane cover. The open diameter of the cone is 15 mm. A central lumen allows for over-the-wire placement. The cone is inserted via the jugular vein through a 10-F profile catheter with a radiopaque band on its end.

drip infusion nor iced saline was used. The filter was released by maintaining the position of the pusher while retracting the sheath at the target site. This filter does not shorten when it opens; this allows for accurate deployment at the target. Follow-up digital subtraction angiography of the IVC was performed in both frontal and lateral projections to assess for filter alignment with the caval axis and to confirm the position of the filter with respect to the renal veins (Fig 2). The sheath was then removed, and hemostasis was achieved. Subsequent anticoagulant therapy was commenced at the discretion of the referring physician.

Filter Removal

Filter removal was performed when it was deemed that the patient could safely resume full and uninterrupted anticoagulant therapy. In some patients, a trial of anticoagulation was performed before planned filter removal to avoid the need for filter reinsertion. Any anticoagulant therapy was subsequently reversed at the time of removal. Therapy with warfarin sodium (Coumadin; DuPont Pharma, Mississauga, Ontario, Canada) was maintained before scheduled filter removal until the international normalized ratio was less than 1.3. In patients receiving dalteparin sodium (Fragmin; Pharmacia, Mississauga, Ontario, Canada), the scheduled dose prior to filter removal was withheld.

Removals were performed with standard aseptic technique and conscious sedation protocols similar to those used in filter insertion. All procedures were performed via the right jugular vein with real-time US control. Initially, a 5-F pigtail or multipurpose catheter, advanced over a guide wire, was placed in a location below the filter so that digital subtraction angiography of the vena cava could be performed in both frontal and lateral projections. The angiograms were assessed for filter position and tilt with respect to the caval axis and to identify trapped thrombus. Following insertion of a 0.035-inch Amplatz extrastiff straight guide wire (Boston Scientific, Mississauga, Ontario, Canada), the 10-F retrieval sheath was placed. It was occasionally necessary to predilate the tract with a 10-F Coons dilator (Cook Canada). The retrieval cone (Fig 3) was then advanced through the sheath and docked with the filter tip so that the filter could be retracted into the sheath and removed.

It was sometimes necessary to advance a 0.035-inch angled guide wire (Terumo; Sultzer Medical, Mississauga, Ontario, Canada) or a 5-F multipurpose catheter (Cook Canada) to facilitate the docking procedure. The guide wire could be advanced through the central lumen of the retrieval cone, whereas the 5-F multipurpose catheter could be introduced through

the retrieval sheath. With increased experience, the procedure was changed so that the initial catheter was selectively placed toward the side of the filter at which the shortest distance between the filter tip and the caval wall was seen at the time of initial angiography. The retrieval sheath was subsequently advanced over a 260-cm-long Amplatz wire. With this technique, any subsequent additional manipulations to dock the cone and filter became unnecessary.

Following removal, a repeat vena cavogram was obtained to assess for procedural trauma or any other complication related to filter residence. The filters were examined for trapped thrombus, endothelium formation, and mechanical damage. The sheath was then removed and hemostasis was achieved. Anticoagulant therapy was restarted under the direction of the referring physician or attending hematologist. The filters were returned to the manufacturer (NMT Medical) so that a complete assessment of device integrity could be performed.

Follow-up

Abdominal radiography 1 and 7 days after placement, then yearly, was recommended per our protocol for follow-up after placement of permanent IVC filters. No other routine follow-up imaging studies were performed because this device was placed on a compassionate basis, not under the confines of a scientific study protocol. However, in any patient in whom an adverse event was clinically suspected, appropriate imaging studies were performed (Fig 4). In patient 10 and all subsequent patients, routine follow-up abdominal radiographs were obtained to assess for possible filter migration. This change in protocol was instituted after identification of an episode of asymptomatic migration of the filter in patient 9. It was specifically requested that these radiographs be sent directly to the author to enable direct comparison of the position of the filter on subsequent radiographs with its position on radiographs obtained at the time of placement.

Several of the patients in this series underwent repeat radiologic examinations after filter removal as part of their routine medical care. When available, images from these examinations were evaluated to identify any postinsertion or removal complications. Clinical follow-up of patients after filter removal was achieved by means of the author's review of subsequent, forwarded medical notes or by direct telephone contact with the patient. On all images, filters were evaluated for tilt, migration, trapped thrombus, and caval perforation. During follow-up visits, patients were evaluated for signs or symptoms of insertion-site or vena caval thrombosis and PE. All radiologic images were evaluated by the author, and all clinical examinations were performed by the referring physician.

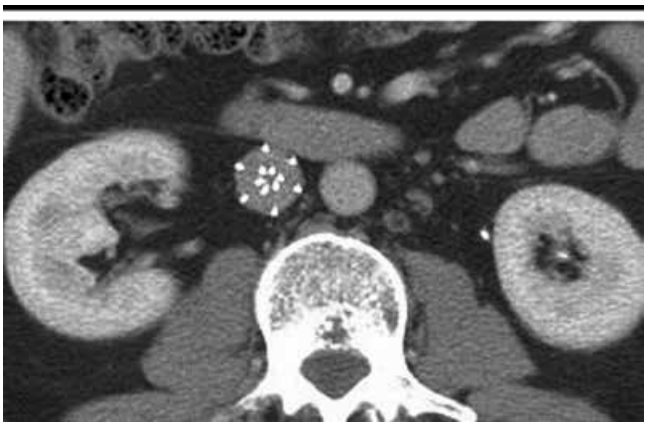


Figure 4. Follow-up transverse contrast material–enhanced spiral computed tomographic (CT) scan obtained as part of this patient's routine medical care 2 weeks after placement of an RNF shows the filter to be in good position, with no associated complication.

RESULTS

Placement of a temporary filter was requested in a total of 34 patients. In one patient, the corrected caval diameter measured 33 mm on the vena cavogram. The referring physician did not want placement of a permanent filter, so no filter was placed in that individual. In one patient with DVT who was scheduled for orthopedic surgery, there was congenital interruption of the vena cava with hemiazygous continuation, so no filter was placed. In all other instances, patients consented and received the RNF (Table 1). Mean patient age was 53 years (range, 18–83 years). There were 16 male and 16 female patients. A diagnosis of DVT was confirmed with color Doppler US in 23 patients; 18 patients had right-sided DVT, and five patients had left-sided DVT. A diagnosis of PE was confirmed in 15 patients at CT angiography.

In four of 26 patients in whom anticoagulant therapy was contraindicated, it was contraindicated because of an underlying coagulopathy. In two patients anticoagulant therapy was contraindicated because the patient had recently undergone surgery, and in 18 patients it was contraindicated because the patient was scheduled to undergo surgery. Four patients had experienced a complication during anticoagulant therapy. In two patients at high risk for PE, filters were placed prophylactically. One filter was placed in a patient with pulmonary hypertension and multiple pulmonary emboli. Filters were placed in two patients in whom pulmonary CT angiograms were initially interpreted as positive for PE by the on-call body imaging staff but in whom final dictated radiology department reports indicated no PE. One of these patients had a remote history of DVT, so the filter was temporarily left in place. In the other patient there was no evidence of DVT, so the filter was removed at 5 days.

Sixteen patients had been given an underlying diagnosis of malignant neoplasm. Patients were referred from the departments of orthopedic surgery (n = 9), surgical oncology (n = 6), general surgery (n = 3), respirology (n = 3), intensive care (n = 2), internal medicine (n = 4), nephrology (n = 2), cardiology (n = 1), neurosurgery (n = 1), and medical oncology (n = 1) (Table 2). Fifteen patients (47%) received concomitant anticoagulant therapy for some period of time while the filter was in place.

Filter Insertion

In one instance, the filter could not be advanced through the introducer sheath. It was unclear whether the problem was that the filter had been loaded incorrectly into the sheath at the time of packaging or if there was inadvertent disengagement of the pusher at the time of insertion. In that patient, the sheath was removed, a new puncture was made, and

TABLE 1
Patient Data

Patient No./Age (y)/Sex	Underlying Diagnosis	Proven DVT	Proven PE	Indication for Filter Placement	Filter Retrieved, Duration of Filter Presence (d)	Confirmed Trapped Thrombus	Patient Outcome
1/55/M	Colon cancer	Yes	Yes	Placed after resection for possible repeat surgery for small bowel obstruction	Yes, 10	Yes	No disease progression
2/35/F	Leukemia	Yes	No	Thrombocytopenia, respiratory failure	No, 41	No	Deceased
3/78/F	Colon cancer	Yes	Yes	Placed before bowel resection	Yes, 29	No	No disease progression
4/22/F	Pyonephrosis	No	Yes	Bilateral nephrostomy, then lithotripsy	Yes, 50	No	Resolution of disease
5/28/M	Crohn disease, giant cell sarcoma	Yes	No	Gastrointestinal bleeding (spontaneous)	Yes, 75	No	Stable
6/30/M	Mesenchymal sarcoma	Yes	Yes	Placed before resection of primary pelvic tumor	No, 59	No	Deceased
7/84/M	Hip fracture, stroke, bladder outlet obstruction	Yes	No	Femoral pseudoaneurysm secondary to carotid stent placement	Yes, 83	No	Ongoing bladder problems (prostatic hypertrophy)
8/58/F	Polyarteritis, pulmonary aspergillosis	Yes	No	Gastrointestinal bleeding secondary to gastric erosions	No, 15	No	Deceased
9/61/M	Coronary artery disease, myocardial infarction	Yes	Yes	Puncture-site complication following emergency coronary artery stent placement (large retroperitoneal hematoma); filter placed before surgical repair and vascular grafting	Yes, 17	Yes	Stable
10/29/F	Chronic renal failure, renal transplant, acute thrombocytopenia secondary to *Escherichia coli* infection	Yes	No	Intraabdominal bleeding after hemicolectomy, thrombocytopenia, and acute renal failure (of transplant)	Yes, 34	Yes	Complete recovery of renal function, reversal of iliostomy
11/70/M	Chrondrosarcoma	Yes	No	Placed before resection of primary tumor	Yes, 65	No	Tumor free
12/37/F	Postpartum hemorrhage, multisystem failure	Yes	No	Cardiac arrest, liver and renal failure, fourth-degree vaginal tear with bleeding	Yes, 21	No	Recovered
13/32/F	Osteosarcoma	Yes	No	Placed before resection of primary tumor	Yes, 71	No	Tumor free
14/67/F	Pelvic sarcoma	Yes	No	Placed before resection of primary tumor with vascular reconstruction	Yes, 55	No	Developed metastatic disease
15/71/F	Lymphoma	No	Yes*	Chemotherapy, thrombocytopenia	Yes, 5	No	Remains in hospital with multiple medical problems†
16/50/M	Chronic renal failure but no dialysis	Remote history of DVT	Yes*	Development of buttock hematoma during warfarin therapy (international normalized ratio, 2.3)	Yes, 70	No	Resolution of disease
17/33/M	Crohn disease	Yes	No	Intraabdominal abscess; filter placed before percutaneous drainage and bowel resection	Yes, 40	No	Resolution of disease
18/46/F	Retroperitoneal sarcoma	Yes	No	Placed before surgical resection of primary tumor	Yes (surgically), 11	No	Stable
19/44/M	Lung cancer	No	Yes	Placed before surgical resection of primary tumor	Yes, 61	No	Tumor free
20/77/F	Colon cancer	No	Yes	Gastrointestinal bleeding during warfarin therapy; filter placed before surgical resection of primary tumor	Yes, 49	Yes	Stable
21/70/F	Colon cancer	No	Yes	PE 3 mo before planned liver resection	Yes, 21	Yes	Stable
22/65/M	Pelvic chondrosarcoma	Questionable‡	No	Placed before surgical resection (patient thought to be at high risk for postoperative DVT given planned vascular reconstruction)	Yes, 14	No	Tumor free
23/49/M	Pulmonary hypertension	Yes	Yes	Newly diagnosed pulmonary hypertension thought to be because of recurrent PE, poor pulmonary reserve	Yes, 77	No	Stable; being considered for embolectomy†
24/47/F	Squamous cell carcinoma of anus	Questionable‡	No	Placed before surgical biopsy of pelvic nodal mass	Yes, 134	No	Slowly progressive metastatic disease
25/74/F	Periprosthetic fracture	Yes	No	Placed before surgical revision	Yes, 91	Yes	Recuperating†
26/80/M	Total knee replacement	Yes	No	Postoperative bleeding at surgical site	Yes, 103	No	Ongoing bleeding; anticoagulant therapy stopped†
27/82/F	Periprosthetic hip fracture	No	Yes	Placed before surgical revision	Yes, 91	No	ND§
28/61/M	Osteoarthritis	Yes	No	Placed before total hip replacement	Yes, 83	No	ND§
29/50/M	Leg osteosarcoma	No	Yes	Chemotherapy followed by surgical resection	NA‖	NA‖	NA‖
30/18/F	Cerebral palsy	No	Yes	Upper gastrointestinal bleeding secondary to severe esophageal ulceration	NA‖	NA‖	NA‖
31/71/F	Hemorrhagic stroke	Yes	Yes	Hemorrhagic stroke	NA‖	NA‖	NA‖
32/35/M	Subdural hematoma	No	Yes	Recent neurosurgery	NA‖	NA‖	NA‖

* On false-positive CT scan.
† At time of writing.
‡ At magnetic resonance (MR) imaging.
§ ND = no data.
‖ NA = not applicable (filter in place at time of writing).

a filter was placed without further difficulty. In another case, the filter was incompletely advanced out of the sheath, causing the leg hooks to engage the sheath. It was possible to recapture the filter tip with the stabilizer arm and then push the filter out of the sheath. This filter did remain in an infrarenal position. All other filters were placed in an infrarenal position without incident. Twenty filters were placed via the left femoral vein, and 12 were placed via the right.

In the placement of 17 (74%) of the first 23 filters, there was some difficulty in releasing the filter legs from the splines of the stabilizer arm. This was overcome by moving the introducer sheath in a gentle twisting motion. This problem had not been encountered in animal testing. Investigation by employees of NMT Medical revealed that the polishing process during manufacturing resulted in a "rolling over" of the edges of the splines, which caused the filter legs to tend to catch when the device was angulated at the time of attempted release. After the tumbling process was changed, the release problem did not recur.

Tilt of the filter with respect to the caval axis (defined as tilt > 15°) was encountered in two (6%) of 32 deployments. The tilt was 20° and toward the side contralateral to the venous puncture in both cases. Each instance of tilt occurred in the first 23 placements, with associated difficulty in release from the splines.

Complications and Filter Removal

No patient developed a substantial puncture-site hematoma or any other complication related to filter insertion or removal. No patient developed symptomatic PE or insertion-site DVT following filter placement or removal (Table 3). One patient with a preoperatively placed filter experienced left-sided hemiplegia 10 hours after surgical revision of a fractured hip prosthesis. Her symptoms completely resolved, and a thorough neurologic evaluation revealed that she had had a transient ischemic attack unrelated to the filter. The filter in this patient was found to contain a small thrombus at the time of an abdominal CT examination.

Thrombus trapped within the filter was encountered in five additional patients at the time of filter removal, for a total of seven (22%) of 32 patients. In three patients the thrombus burden was small, and the filters were removed with a standard technique and the standard retrieval sheath (Fig 5). Two filters were found to contain a large thrombus at the time of elective removal. In one patient, the filter was also noted to have migrated approximately 4 cm cephalad at the time of planned elective removal 17 days after insertion (Fig 6a, 6b). In retrospect, a lesser degree of migration was noted on a follow-up abdominal radiograph that had been obtained 4 days earlier; however, the migration had not been indicated in the typed radiology report.

After extensive discussion with the patient and referring physicians, it was decided that filter removal should be attempted. In this case, a 20-F vascular sheath (Cook Canada) was inserted and the RNF sheath was placed through it. The filter and thrombus were removed together (Fig 6c–6e). Although the patient was asymptomatic, CT angiography of the pulmonary arteries and CT venography of the IVC were performed to assess for local residual thrombus or PE. No evidence of either was seen. Two other patients underwent CT angiography of the pulmonary arteries at the time of filter removal (one filter had a trapped clot, and one did not); there was no evidence of PE in either of these patients.

Three patients died of their underlying disease with the filter in place 15 to 59 days (average, 38 days) after placement without clinical evidence of PE. Autopsy information was not available for any of these patients. One filter was removed intraoperatively as a result of a surgical mishap during attempted resection of a large retroperitoneal sarcoma. Twenty-four filters were removed 5–134 days (mean, 53 days) after insertion; as of this writing, four remain in place for planned removal. All attempted filter removals were successful (Fig 7). Once the sheath was in place, filter retrieval always took less than 2 minutes. Several patients noted momentary mild epigastric or back pain at the time the filter was removed. Otherwise, the majority felt only some manipulation of the jugular venous sheath.

Follow-up

Many patients continue to undergo medical and radiologic follow-up as a result of their underlying disease process (Table 4). Records from medical visits and/or abdominal CT examinations were available in 22 (92%) of the 24 patients who had undergone filter removal. The average length of follow-up was 223 days (range, 4–522 days). Follow-up data included information obtained from abdominal CT examinations in seven patients, chest CT examinations in four patients, and clinical care visits or telephone interviews in 20 patients. One patient developed clinical symptoms suggestive of PE 133 days after filter removal. However, repeat CT angiography of the lungs did not depict PE.

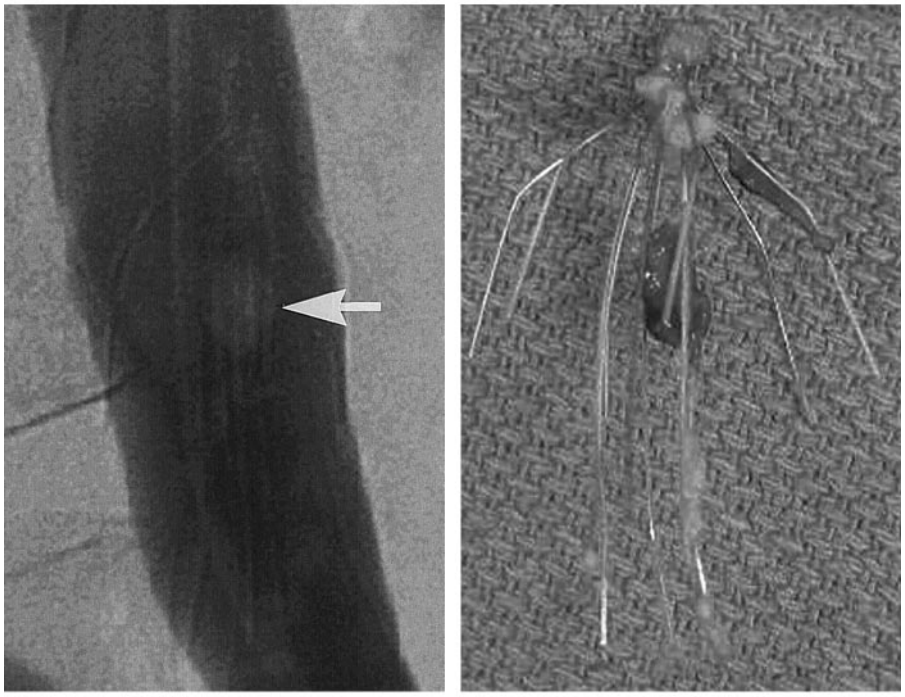
As of this writing, no other patient has developed clinical symptoms or imaging findings suggestive of PE, recurrent DVT, or any caval abnormality. One patient experienced recurrent hemorrhage at the surgical site (of a total knee replacement) 8 days after the filter was removed and therapy with dalteparin sodium had been reinstituted. This patient had previously tolerated a 2-week course of dalteparin sodium before filter removal. The indication for filter placement in this patient was PE without documented DVT. Because it had been 100 days since PE occurred, the attending hematologist believed it was safe to discontinue anticoagulant therapy.

TABLE 2
Patient Demographics

Characteristic	No. of Patients
Diagnosis	
DVT	23
PE	15
Reason for filter placement	
Anticoagulant therapy contraindicated	26
Anticoagulant therapy had resulted in complications	4
Coagulopathy	4
Prophylaxis	2
Poor pulmonary reserve	1
Subsequent surgery	18
Referring department	
Orthopedic surgery	9
Surgical oncology	6
Internal medicine	4
General surgery	3
Respirology	3
Intensive care	2
Nephrology	2
Neurosurgery	1
Medical oncology	1
Cardiology	1

TABLE 3
Number of Patients with Complications

Complication	No. of Patients
Failure (PE with filter in place)	0
Insertion site thrombosis	0
IVC thrombosis	0
Filter migration (>2 cm)	1
Filter tilt (>15°)	2



a. b.

Figure 5. Thrombus removal. **(a)** Vena cavogram obtained with a 5-F multipurpose catheter inserted via the right internal jugular vein at the time of filter removal (10 days after placement) reveals a small trapped embolus within the filter (arrow). **(b)** Gross specimen obtained after removal of filter and embolus with a standard 10-F sheath. Note embolus trapped by filter legs.

TABLE 4
Patient Follow-up

Outcome	No. of Patients
Intraoperative filter removal	1
Death	3
Percutaneous filter removal	24
Follow-up visit, follow-up radiology	22*
Clinic visit	20
CT of abdomen	7
CT of thorax	4

Note.—Thirty-two filters were placed in 32 patients.

* Follow-up records were available in only 22 of the 24 patients who underwent percutaneous filter removal.

DISCUSSION

The RNF IVC filter is manufactured by NMT Medical. Constructed of nitinol, this filter is modeled after the dual-level structure of the Simon nitinol filter, which NMT Medical also manufactures. Several designs of a temporary retrievable filter were investigated before the current design for the RNF was conceived in 1998. One of the key features of the RNF that allows for retrieval many months after implantation is the hook design. The hooks of this filter were specifically designed, modeled, and tested to resist filter migration. The RNF underwent extensive benchtop and animal evaluation before it was first placed in a human patient (16).

Interest in a retrievable IVC filter has intensified since the first reported successful retrieval of an Amplatz filter (William Cook Europe, Bjaeverskov, Denmark) by Darcey et al in 1986 (17). However, this device was withdrawn from sale as a result of a high rate of vena caval thrombosis (18). There are currently a variety of tethered removable filters available in North America; however, they are not commonly placed as a result of their intrinsic design limitations.

The medical need for a retrievable filter design is demonstrated by the off-label use of currently approved permanent filters. Cope et al (19) described partial deployment of a Bird's Nest filter (Cook, Bloomington, Ind) during thrombolysis of iliocaval thrombus. The filter was safely removed 6.5 hours later (19). More recently, Nutting and Coldwell (20) completely deployed a TrapEase filter (Cordis, Miami, Fla), also for temporary protection during thrombolysis. Nutting and Coldwell described using a combined jugular and femoral venous approach to retrieve the filter after the procedure (20).

Although these maneuvers have proven to be successful in these case reports, they clearly contravene the manufacturer's instructions for use and place the patient at risk for a complication or failure of removal. A more common indication for filter removal is filter migration, either occurring at the time of implantation or seen at follow-up (21–23). Perhaps less common as an indication for removal is filter infection. Millward et al (24) reported a death attributed to an infected filter (Vena Tech; B Braun, Mississauga, Ontario, Canada). More recently, Lin et al (25) reported the successful removal of an infected Gunther Tulip filter 14 days after implantation. Another indication well suited for a retrievable IVC filter is that of trauma (26,27).

The Gunther Tulip filter was approved for both permanent placement and retrieval in Canada in March 1998. In the United States, it is approved for permanent use. Although the instructions for use state that the filter should be removed by 10 days, Millward et al (28) have reported removal up to 25 days after implantation. However, in an earlier animal study, one of 21 Gunther Tulip filters could not be retrieved 14 days after insertion as a result of adherence to the caval wall (29). Recently published data from the registry of the Canadian Interventional Radiology Association regarding the placement of 91 Gunther Tulip filters currently represent the most extensive experience with that device (28). In that series, one filter could not be retrieved because the hook could not be engaged by the snare. Fifty-two filters were successfully removed at a mean of 9 days after placement. Of the 37 patients who were followed up, four required reinsertion of a permanent filter at a mean of 78 days after removal. Filters were not removed from 17 patients as a result of ongoing contraindications to anticoagulant therapy (28). These results support the need for a filter that can be removed well beyond a 10–15-day window.

The perfect temporary IVC filter would be one that has high clot-trapping efficacy but a low incidence of caval thrombosis. It would have to be nonmigratory yet be able to be retrieved at a time distant from the time of insertion. Finally, there should be no external tether to limit patient mobility or serve as a nidus for infection. While intimal hyperplasia is expected to occur with any implanted device, there are filter design factors that

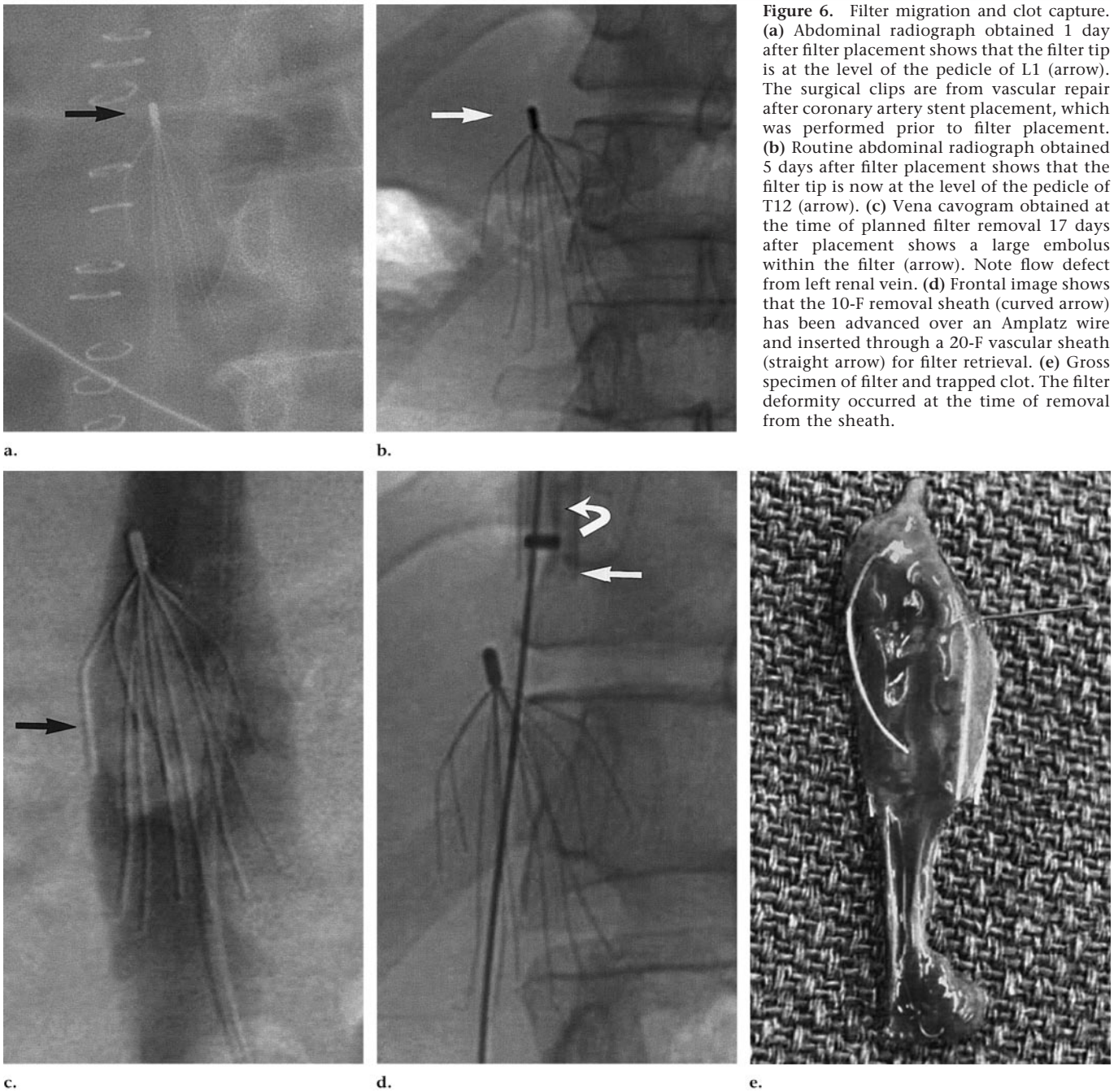
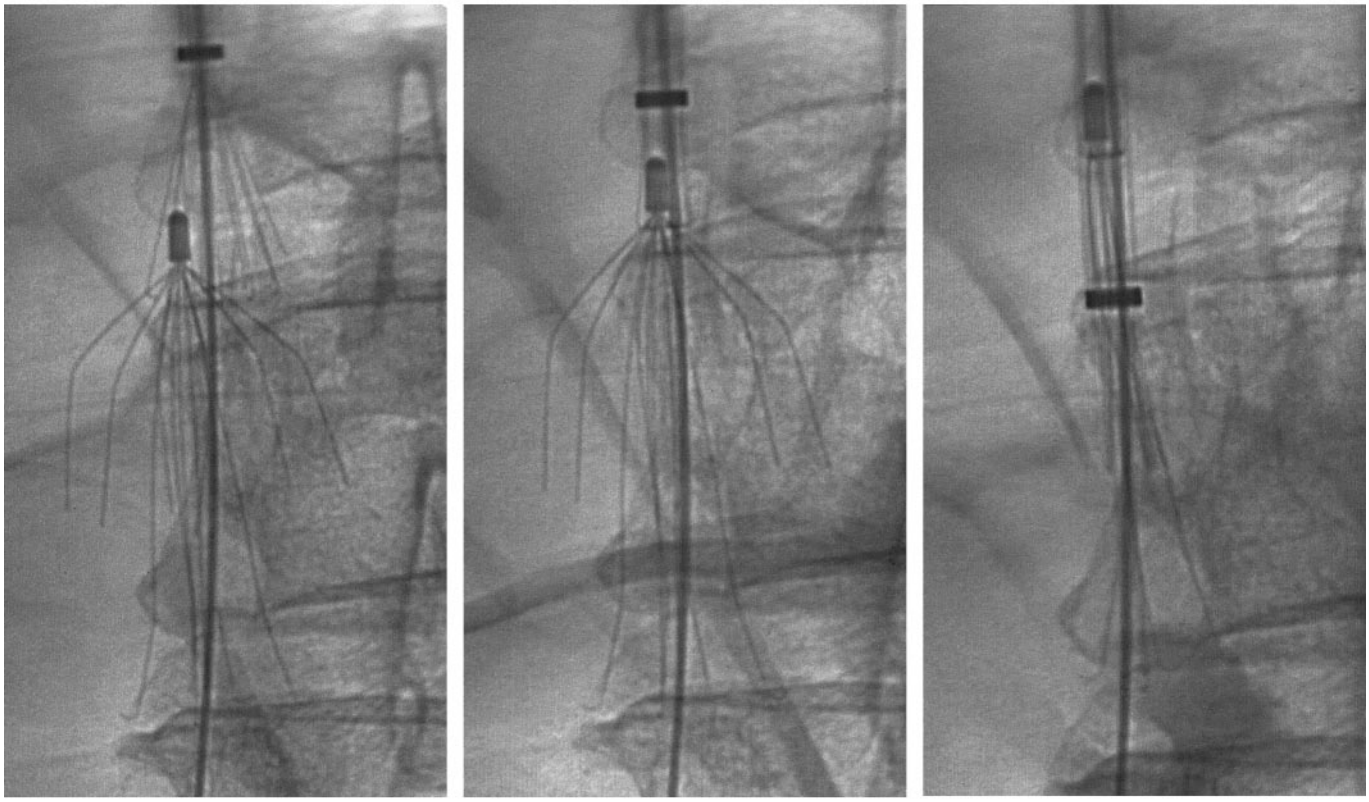


Figure 6. Filter migration and clot capture. **(a)** Abdominal radiograph obtained 1 day after filter placement shows that the filter tip is at the level of the pedicle of L1 (arrow). The surgical clips are from vascular repair after coronary artery stent placement, which was performed prior to filter placement. **(b)** Routine abdominal radiograph obtained 5 days after filter placement shows that the filter tip is now at the level of the pedicle of T12 (arrow). **(c)** Vena cavogram obtained at the time of planned filter removal 17 days after placement shows a large embolus within the filter (arrow). Note flow defect from left renal vein. **(d)** Frontal image shows that the 10-F removal sheath (curved arrow) has been advanced over an Amplatz wire and inserted through a 20-F vascular sheath (straight arrow) for filter retrieval. **(e)** Gross specimen of filter and trapped clot. The filter deformity occurred at the time of removal from the sheath.

would limit the associated adverse effects. It is the author's hypothesis that the ability to retrieve a filter without concern for the amount of hyperplasia requires a filter to have little metal in contact with the caval wall.

Filter design is also important. If one looks at the design of the Gunther Tulip filter or the TrapEase filter, it becomes evident that the complex metal matrix would serve to anchor the filter in place when hyperplasia occurs. On the other hand, the design of the RNF allows for the filter arms to slide out of any potential sleeve once the elastic leg hooks have been removed from the caval wall. The animal data demonstrating the ability to remove an RNF at 22 weeks, coupled with the fact that one was removed from a human at 134 days, suggest that there is no upper limit to the time of retrieval with the current design. In contrast, studies of virtually all other filter designs included cases in which the filter could not be removed 2 weeks after insertion (15,29). Given that intimal hyperplasia stabilizes at approximately 3–6 weeks, one would expect that beyond that time filter fixation is not an issue.

The simple fact that a retrievable device is available is of limited clinical importance if that device must be removed by 10–15 days after placement. In the ideal situation, a patient could safely undergo anticoagulant therapy after surgery. However, even from this relatively small series, it is clear that many patients have more complex situations and require a much longer period of time before they can be



a. b. c.

Figure 7. Sequence of vena cavograms illustrates the technique of removing a filter with a wire. **(a)** The retrieval cone is advanced over a wire, **(b)** the filter arms are engaged, and **(c)** the filter is retrieved.

maintained on uninterrupted therapeutic doses of anticoagulants. Several of the patients referred from orthopedics who underwent routine surgery to install a joint prosthesis had not resumed full ambulation even at 90 days after filter placement. Patients referred from general surgery often require follow-up procedures (such as percutaneous abscess drainage or a second surgical procedure) after surgery.

Although the most common device used for percutaneous removal of foreign bodies is some type of snare, techniques used with this device are not always successful. In the series of Millward et al (28), there was one failed retrieval as a result of the position of a Gunther Tulip filter hook with respect to the caval wall. In spite of moderate angulation in several cases in this series, all filters were easily and successfully retrieved. The urethane-covered claws modeled into a cone shape enabled the efficient engagement and retrieval of the RNF. The ability to pass a 0.035-inch wire through the central lumen of the cone greatly facilitated the docking procedure when there was no straight-line access to the filter tip. As our experience grew, changes in technique occurred. During the final four retrievals, the catheter was intentionally manipulated toward the side of filter tilt and the cone was always advanced over a wire. In this way, no additional maneuvers were required to engage the filter and cone.

There was a single occurrence (3%) of asymptomatic filter migration in this series of 32 patients. Migration is typically defined in the literature as movement greater than 2 cm. The reported incidence has been shown to vary between less than 1% and 13% and typically includes spontaneous migration to the heart (4,24,30,31). In our study patient, the filter was seen to be in a position several centimeters cranial to the insertion position on the radiograph obtained 5 days after insertion. However, the typed radiology report simply stated "An IVC filter is in place." At the time of planned removal at 17 days, the filter was seen to have migrated an additional 2 cm craniad. The vena cavogram obtained before removal revealed a large trapped embolus. It was possible to remove this filter and trapped embolus with the standard retrieval cone introduced through a 20-F sheath. That event was reported to the Health Protection Branch and to our institutional review board, and the consent form was subsequently modified to include information on it.

As a precaution, all subsequent patients underwent follow-up abdominal radiography to assess for filter migration. This fact was emphasized to both the referring physician and the patient. It was requested that all radiographs be sent directly to the author so that he did not have to rely on the dictated report. No other instance of filter migration was encountered. In one patient, several filter arms were seen to lie outside of the vena cava (at venography and CT). However, this patient was asymptomatic, and the filter was easily removed (at 134 days). This patient had undergone an abdominal surgical procedure 2 days after filter placement. Filter penetration of the caval wall has been reported to occur with an incidence of 9% (4).

Although in the present study, filters were placed on a compassionate basis—outside a formal scientific trial—patients were followed up prospectively. Given that this study represents the initial human use of a new medical device, pa-

tients were also promptly and thoroughly examined for any questionable complication. A number of patients underwent CT examination of the abdomen after filter placement and removal to assess for local complications; none was encountered.

In this series of 32 patients, filter efficacy was demonstrated by the fact that there were no episodes of PE and that trapped embolus was seen within the filter in seven cases. Complications such as caval occlusion or insertion-site thrombosis did not occur. The filter was successfully removed in all patients, even when a large trapped thrombus was present. The average time to filter removal in our experience (53 days) is well beyond the residence period for other removable/retrievable filters. The complexity of the clinical situation in these patients is shown by the need to maintain the filter in place for more than 100 days in two of our patients. The ability to remove this filter after such lengthy residence will likely prove to be important and will allow the majority of patients to receive a temporary filter instead of the permanent device used as part of the current standard of treatment. A large multicenter scientific study is warranted to further substantiate the role and value of this retrievable filter.

In conclusion, this preliminary, special-access use of the RNF, a retrievable IVC filter, suggests that the filter can easily be delivered via a femoral vein. It can be removed percutaneously up to 134 days after insertion without difficulty. No substantial complications were encountered in this series. Specifically, there were no documented incidents of PE, caval thrombosis, or insertion-site DVT with the filters in place. Retrieval via the jugular vein allows for removal of filters with small-to-large trapped thrombi.

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EXHIBIT 20

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS

HENRY KILVER AND JUDY KILVER, individually and as husband and wife,	)	
Plaintiffs,	)	
vs.	)	No. 1:13-CV-01219-MMM-JAG
C.R. BARD, INC., a foreign corporation, BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, and does 1 through 100, inclusive,	)	
Defendants.	)	

VIDEOTAPED DEPOSITION OF
Robert Carr

Phoenix, Arizona
December 19, 2014
8:04 a.m.

LEO T. MANKIEWICZ, CR, RMR, CRR
Arizona Certified Reporter
Certificate No. 50778

vena cava distension, does not make a device safer?

MR. LERNER: Objection to form.

THE WITNESS: I'm saying that that is a contributor to it. There are many other things that went into those -- to the design to resist migration.

BY MR. BRENES:

Q Okay, and you refuse to admit it makes the device safer.

A I refuse to admit, on its own, it makes the device safer. There are other things that go into it.

Q Okay. Let's talk about, what other things help prevent migration, in the event of vena cava distension?

A The strength of the hooks, the shape of the hooks, the engagement into the wall, how it distended, where it distended, what caused the distension.

Q Okay, the last three things you just said aren't design issues, are they?

A Of course they're design issues.

Q Okay. Sir, what changes were made between the Recovery and the G2 filter to prevent the device from migrating as much as of the Recovery Filter did?

MR. LERNER: Objection to form, outside the scope of the notice.

THE WITNESS: The arms were made longer, the resting diameter of the filter was made larger than the Recovery --

BY MR. BRENES:

Q The leg span?

A The resting leg span, yes. Not the -- the hooks were changed. The diameter of the wire was increased.

Q And that's on the hooks?

A Yes.

Q Because that makes them stronger and more able to resist a clot challenge, correct?

A Yes.

Q So does increasing the diameter of the hooks and the resting leg span, those two design changes that Bard made between the Recovery Filter and the G2 filter, make it a safer device?

MR. LERNER: Objection to form, outside of the scope of the notice.

THE WITNESS: It make it have a higher migration resistance, yes.

BY MR. BRENES:

Q Makes it less likely to migrate, right?

MR. LERNER: Objection to form, outside the

scope of the notice.

THE WITNESS: Due to pressure, yes.

BY MR. BRENES:

Q And did Bard confirm that, in its own testing?

MR. LERNER: Objection --

THE WITNESS: Ultimately, yes.

MR. LERNER: -- to form, outside the scope of the notice.

THE REPORTER: I'm sorry, I didn't get the answer, there.

THE WITNESS: Yes.

BY MR. BRENES:

Q I was going to ask whether there were other design changes, from the Simon Nitinol Filter to the G2 -- to the Recovery Filter. You raised the point that the diameter of the hooks affects migration resistance, right?

A The diameter and shape.

Q Okay. Was the diameter of the hooks from the Simon Nitinol Filter reduced to what was in the Recovery Filter?

A The Recovery Filter's hook diameter is smaller than the SNF diameter.

Q Which made it less able to resist migration,

EXHIBIT 22

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

KEVIN PHILLIPS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Civil Action No.
	)	
C. R. BARD, INC., et al.,	)	3:12-cv-00344-RCJ-WGC
	)	
Defendants.	)	
_____	)	
AND RELATED CASES.	)	

VIDEOTAPED DEPOSITION OF ANDRZEJ CHANDUSZKO
Phoenix, Arizona
October 10, 2013
9:30 a.m.

REPORTED BY:
Robin L. B. Osterode, RPR, CSR
AZ Certified Reporter No. 50695

obviously are there a means to implement it. So in a case of this particular filter and this particular design, it looks like the -- having the filter cut out of a tube, it did allow to implement some new features that would be difficult, otherwise, to implement on a, say, filter made out of a wire.

Q. So is it your testimony that you could not have done a penetration limitator on Bard's previous recover -- or IVC filters, because they were not made out of tubing?

A. No.

Q. That's not your testimony?

A. No.

Q. Okay. So could Bard have instituted the penetration limitator in the earlier filters?

A. As hypothetically?

Q. I'm asking you as an engineer?

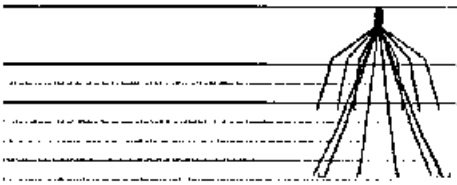
A. If there was, well, you need to have an idea first. So if there was no idea, then you couldn't. You require certain knowledge, you know; they didn't build the Rome in one day, so to speak. So I don't know whether they could have or --

Q. Let's say you had the idea you had the goal let's improve penetration resistance or perforation resistance; could you have instituted a penetration

limiter on the earlier design of the IVC filters?
A. Just from purely technical standpoint?
Q. Uh-huh.
A. You could have done it in some ways. I don't know would be a good way or not, but yes.
Q. Okay.
A. You could have done it.
Q. By the way, how long did you meet with Ms. Daly to prepare for today's deposition?
A. Like I mentioned, I think it was two or three hours.
Q. Were there any phone calls as well?
A. During the deposition?
Q. No, to prepare for the deposition.
A. Sorry. No.
Q. All right.
A. I don't remember any.
Q. Did you have any other involvement with the Denali filter, other than what we talked about?
A. I was on the project from the beginning of the project to the -- not to the end, but for the most part.
Q. When did that project start?
A. Just going to guess, probably 2010 sometime.

EXHIBIT 23

Recovery® Filter System for use in the Vena Cava



ENGLISH

Information for Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The *Recovery* Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *Recovery* Filter provide excellent filtering efficiency and allow percutaneous placement through a standard 7 French I.D. single-spout introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The *Recovery* set is designed to introduce through its 46 cm, 7 French I.D. introducer catheter using a flexible, internal pusher wire. A part at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back while the pusher wire handle is stationary and release the filter and allow it to recover to its predetermined shape. The centering system allows the *Recovery* Filter to be deployed with the filter apex centered and prevents the legs from crossing.

The *Recovery* Filter is designed to act as a permanent filter. When clinically indicated, the *Recovery* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *Recovery* Filter's elastic properties allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional *Removal* Procedure for specific removal instructions.)

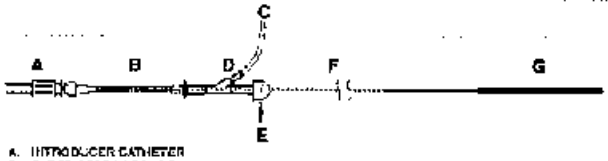
MRI Compatible: The *Recovery* Filter system is MRI safe and nonclinical tests have demonstrated that the device will migrate minimally during the first 4 weeks following implantation. Additional testing has demonstrated that the device will not migrate appreciably during MRI procedures performed under the following conditions: static magnetic field of 1.5 Tesla or less, maximum spatial gradient magnetic field of 720 Gauss/cm or less, and maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg or less for 15 minutes of scanning. Under the scanning conditions described above, the maximum temperature rise of the device is expected to be less than 2°C after 15 minutes of continuous scanning. Artifacts in the MR image caused by the device extend approximately 5 mm from the device when imaged with a gradient echo pulse sequence and a 1.5 Tesla MR system. The MR safety and artifact information was determined through nonclinical testing. The effects of MRI after more than 4 weeks have not been evaluated.

B. Device Description

The *Recovery* Filter System consists of the Filter and Delivery System. The *Recovery* Filter consists of several, shape memory nitinol struts originating from a central hub of wires. These wires form two levels of filtration at the hub: the lower level of filtration and the struts provide the upper level of filtration. The *Recovery* Filter is intended to be used in vena cava with diameters up to 28 mm.

The *Recovery* Filter Delivery System is illustrated in Figure A. The Delivery System consists of a 7 French I.D. introducer sheath and dilator, the *Recovery* filter, a storage tube with saline infusion port, and a pusher system. The *Recovery* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery Filter System



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the *Recovery* Filter.

C. Indications for Use

The *Recovery* Filter System is indicated for use in the prevention of recurrent pulmonary embolism in permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the corrected, inferior vena cava (IVC) diameter exceeds 28 mm the filter must not be inserted into the IVC.

The *Recovery* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with vena cava diameters greater than 28 mm
- Patients with risk of septic embolism

E. Warnings

Recovery Filter Implantation

1. The *Recovery* Filter vena cava filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the vena cava (IVC), as the *Recovery* Filter cannot be safely reloaded into the storage tube.
2. Delivery of the *Recovery* Filter through the introducer sheath is advanced only. Retraction of the pusher wire during delivery could result in dislodgement of the filter, crossing of filter legs or apex, or could prevent the Filter from further advancement within the sheath.
3. The *Recovery* Filter System is designed for femoral approaches only. Never use the *Recovery* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *Recovery* Filter orientation within the inferior vena cava.
4. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer.
5. Only use the *Recovery Cone*® Removal System to remove the *Recovery* Filter. Never re-deploy a removed filter.
6. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.

Recovery Filter Removal

1. Do not attempt to remove the *Recovery* Filter if significant amounts of thrombus are trapped within the filter or if the filter is embedded within the vena cava wall.
2. Use only the Bard *Recovery Cone* Removal System (packaged separately) to retrieve the *Recovery* Filter. Use of other devices has resulted in incomplete removal, pulmonary embolism.

F. Precautions

Recovery Filter Implantation

1. The filter should be placed in the supradistal position in pregnant women and in women of childbearing age.
2. Anatomical variations may complicate filter insertion and deployment. Careful attention to these instructions for use can shorten insertion time and reduce the likelihood of difficulties.
3. Spinal deformations: It is important to exercise caution when contemplating implantation in patients with significant kyphoscoliotic or spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations. This may require advanced techniques to remove the filter.

Recovery Filter Removal

1. Anatomical variations may complicate insertion and deployment of the *Recovery Cone* Removal System. Careful attention to these instructions for use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise caution when contemplating removing the *Recovery* Filter with the *Recovery Cone* Removal System in patients with significant kyphoscoliotic spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations. This may require advanced techniques to remove the filter.

G. Potential Complications

- Migration of the filter. This may be caused by placement in oversized vena cava (diameters exceeding 28 mm) or if proper anchoring techniques are not utilized.
- Perforation of the vena cava wall. This may occur if proper insertion technique is not utilized.
- Caval occlusion. The probability of this occurring should be weighed against the inherent risk/benefit ratio for a patient who is experiencing pulmonary embolism, or who is likely to do so without intervention.

H. Equipment Required

The following equipment is required for use:

One *Recovery* Filter and Delivery System that contains:

- One 46 cm, 7 French I.D. introducer sheath and dilator set
- One storage tube with pre-loaded *Recovery* Filter and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip infusion
- All basic materials for venipuncture: scalpel #11 blade, local anesthesia, drapes, etc.
- An entry kit consisting of a 0.035" 3 mm J-tipped guidewire, entry needle, #11 scalpel and 10-cc syringe is available from C. R. Bard catalog number 410001.

If the physician chooses to percutaneously remove the *Recovery* Filter, the *Recovery Cone* Removal System is available from C. R. Bard, Inc.

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A, Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or iliac vein.

NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush introducer catheter by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.

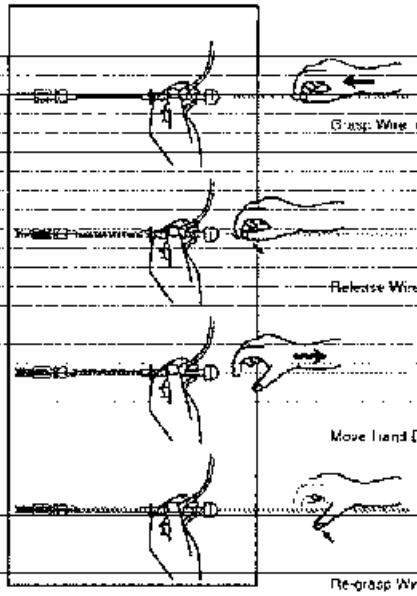
NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be removed to facilitate this. For femoral insertion the introducer catheter tip should be 1 cm. below the lowest renal vein.
10. Remove the filter and delivery system from Kit B.
11. Connect a 500-mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion rate to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to maintain retrograde flow of saline, but not so tight as to prevent the pusher wire from advancing freely.

NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flush into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

Advancement of Filter, Illustrated



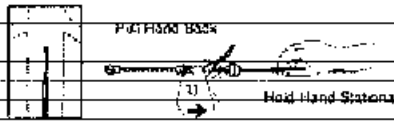
13. Advance the Filter by moving the nitinol pusher wire forward through the introducer catheter, covering the Filter with each forward motion of the pusher wire (Figures B-E). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the pusher wire may be looped, while causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.
14. Cease forward movement of the pusher wire until the Filter tip advances to the radiopaque markers on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

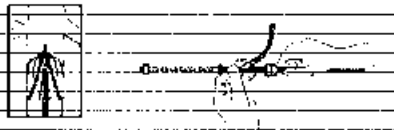
Filter Release/Deployment

15. Deploy and release filter as described below:
    - Figure F: Firmly hold the pusher wire handle.
    - Figure F-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

NOTE: Do not deploy the Filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary Filter by withdrawing the introducer catheter as described below.

Filter Release, Illustrated





How release the Filter by unsheathing it in the IVC as follows:

Position the Filter tip 1 cm below the lowest renal vein.

Figure G: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

- Figure G-1: Unsheathing of Filter in IVC.
- Figure H: The position of the hands at the completion of the unsheathing process.
- Figure H-1: The Filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube and delivery catheter assembly, and pulling back on the pusher wire.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

18. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
19. Remove the introducer catheter and apply radial compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Removal of Recovery Filter

CAUTION: It is strongly recommended that removal of the Recovery Filter be done using the Recovery Cone only.

Equipment Required

The following equipment is required for use:

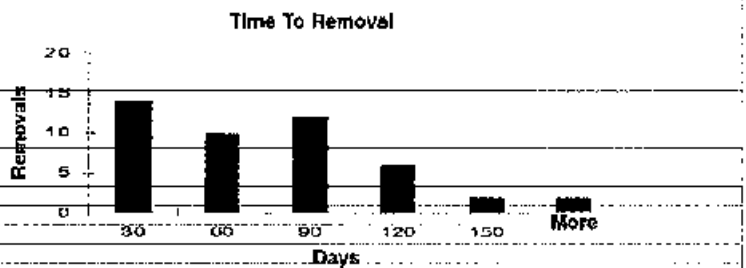
- One Recovery Cone Removal System that contains:
  - One 75 cm, 10 French I.D. delivery sheath and dilator set
  - One Y-adapter with Recovery Cone inner push/pull delivery system
- 1 with 3 mm Hippal Kindwall, 110 cm Rim or larger
- 18 gauge entry needle
- 12 French dilator
- Saline
- Sterile extension tube to clamp clip or S-ring for saline infusion
- All basic materials for percutaneous access: #11 blade, local anesthesia, drapes, etc.

Clinical Experience

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 55 subjects, under the Special Access regulations.

Although essentially only one physician used the device, retrieval was performed by three physicians with different support staff and imaging equipment.

Of the 55 filters implanted, a total of 45 have been retrieved, 6 remain in place, and 4 patients have died with filters in place of causes unrelated to the placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 151 days, average 50 days (see histogram).



Follow-up post retrieval has been an average of 325 days (range 1-951 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One was removed surgically during a cancer operation where the mass was impinging on the filter. The two methods described in the instructions for Use were used to retrieve the filters in all but 4 cases where a larger sheath was used or a snare loop was attempted instead of using the Recovery Cone Removal System. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other serious event reported was a fractured filter arm at 6 days. This filter was placed inferiorly in a pregnant woman during the third trimester at the level of L1/L2. The fracture was believed to be secondary to stresses due to delivery and placement inferiorly, causing severe deformation and embedding of the hook into the body tissue of the vertebrae. The filter was retrieved, minus the hook.

Clinical Experience
Summary Table

Recovery Filters Implanted	55
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	6-89 years (52 years average)
Reason for Filter placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	0
Prophylaxis	2
Time to removal	1-151 days (50 days average)
Follow-up post-removal	1-951 days (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to:	
labor and birth and inferior placement	1
Asymptomatic pulmonary embolism post-removal	1

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of known thrombus.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the Recovery Cone Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #15 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the Recovery Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Predilate the accessed vessel with a 10 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush if necessary by hand or attach to the catheter a location saline drip infusion to maintain the introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the IVC. If there is significant thrombus within the filter, do not remove the Recovery Filter.

Recovery Cone Insertion and Delivery

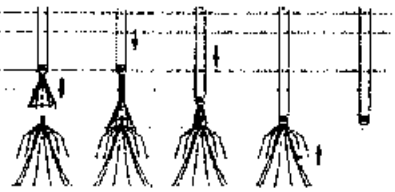
11. Remove the Recovery Cone and pusher assembly from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter.

14. Connect a 500 mL bag or a syringe of saline to the side port of the Y-adapter. Allow the saline infusion to flush around the retracted cone at the adapter for a seconds. Agitate the locking wheel adapter manually to aid in removal of air bubbles from the system. DO NOT use high pressure to prevent the guidewire shaft from detaching freely.
15. Align the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and locking system should be flushed to straighten and minimize friction.
16. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
17. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the Cone by stabilizing the shaft and retracting the catheter.

Capture of Recovery Filter

Filter Removal, Illustrated



18. The capture of the Recovery Filter is illustrated in Figures B-F:

Figure B: After the cone has been opened super ior to the Filter, advance the cone over the Filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anteroposterior fluoroscopic image to confirm that the cone is over the Filter tip.

Figure C: Close the cone over the Filter tip by advancing the introducer catheter over the Cone while holding the pusher shaft stationary.

Figure D: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure E: With the cone collapsed over the Filter, remove the Filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure F: The Filter has been retrieved into the catheter.

Follow-up Venacavagram

19. A follow-up venacavagram may be performed after withdrawing the introducer catheter (typical 7 Fr. inf. of contrast, maximum 15 mL).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variations with respect to the position of the Recovery Filter, guidewire assisted techniques may be used.

Use of a Guidewire

If it is difficult to advance the cone over the Recovery Filter tip, one may use a guidewire to facilitate advancement of cone over the Filter tip.

Withdraw the introducer sheath and cone shaft away from the Filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip, a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the Filter near the Filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 16.

J. How Supplied

Each Recovery Filter is supplied pre-loaded in its storage tube. Each Recovery Filter system is sterile and non-pyrogenic unless package is damaged or opened, and is ready to be used for a single use only. The storage tube and delivery system are pre-assembled. If the Filter is inadvertently discharged, do not attempt to reconstitute or reload it.

Note: Refer to the Recovery Filter accessories and insertion sequences may be performed, retained and disposed of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The Recovery Filter should be stored in a cool, dry place.

K. Warranty

Bard warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard's sole discretion, or refunding your net price paid. Users and non-normal use or defects resulting from misuse of this product are not covered by this limited warranty.

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Labeling Issue Date: 1903

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.

Bard, Recovery and Recovery Cone are registered trademarks of C. R. Bard, Inc. or an affiliate.

U.S. Patent No. 6,007,564 and 6,258,026. Other Patents Pending.

References:

1. ACR Standard For The Performance Of Percutaneous Peripheral Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism : 2003 ;Rev.12; Effective 01/01/03.

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Système de filtre Recovery®
pour utilisation dans la veine cave

FRANÇAIS

Mode d'emploi

Attention : Selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur prescription médicale.

A. Informations d'ordre général

Le filtre **Recovery** représente une nouvelle génération de dispositifs d'occlusion minimale conçus pour la prévention de l'embolie pulmonaire. La conception unique et le matériau de fabrication du filtre **Recovery** lui confèrent une excellente stabilité et permettent sa mise en place pendant de nombreux mois grâce à une gaine d'introducteur angiographique (ID. 7 French standard) avec un minimum de difficultés au point d'entrée. La procédure de mise en place est rapide et simple à réaliser.

Le dispositif général est conçu pour progresser dans la canule d'introduction I.D. 7 French de 40 cm à l'aide d'un fil de poussoir flexible en nitinol. Un capteur à l'extrémité du fil est conçu pour pousser sur le sommet du filtre et un segment taillanté est conçu pour maintenir et orienter correctement les pieds du filtre. Ces composants relient le filtre au fil du poussoir à mémoire de forme de telle façon que progresser le fil, extraire ou avant, jusqu'à l'extrémité distale de la canule, positionne toute la voûte reçoit la plus basse. Lorsque l'extrémité du filtre approche de l'extrémité de la canule d'introduction, elle est positionnée autre les repères radio-opaques situés sur la canule d'introduction. Le canule d'introduction et l'ensemble de mise en place sont alors tirés en arrière sur la poignée **3**. Il du poussoir, afin de retirer la gaine, libérer le filtre et lui permettre de retrouver sa forme prédéterminée. Le système de centrage permet au filtre **Recovery** d'être déployé avec son extrémité pointue et empêche le croisement des pieds.

Le filtre **Recovery** est conçu pour agir en tant que filtre permanent. En cas d'intervention clinique, le filtre **Recovery** peut faire l'objet d'un retrait percutané après implantation, conformément aux instructions fournies pour la procédure de retrait optionnel. Les marqueurs radio-opaques du filtre **Recovery** permettent de tester rapidement et de vérifier à tout moment, avant la procédure, l'état du filtre. Cette évaluation permet d'obtenir des informations sur la position du filtre, la présence de déformations et l'état de la veine cave inférieure (VCI) avant le retrait. Une procédure de retrait optionnel pour des indications spécifiques concernant le retrait.

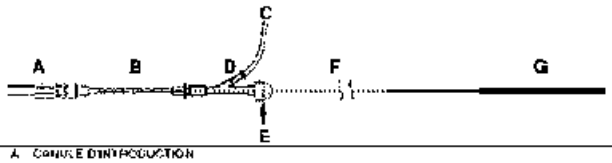
Complications : Le filtre implanté **Recovery** ne présente aucun risque en cas d'IRM. Il n'interfère pas avec et n'est pas affecté par le fonctionnement d'un dispositif d'IRM.

B. Description du dispositif

Le système de filtre **Recovery** se compose du filtre et du système de mise en place. Le filtre **Recovery** est constitué de dards fins en métal à mémoire de forme et d'un manchon central en nitinol. Ces dards se forment deux niveaux de filtration de l'embolie. Les pieds fournissent à niveau inférieur et les pics fournissent le niveau supérieur de filtration. Le filtre **Recovery** est prévu pour une utilisation dans la veine cave à des diamètres allant jusqu'à 28 mm.

Le système de mise en place du filtre **Recovery** est illustré en Figure A. Le système de mise en place se compose d'une gaine d'introducteur I.D. 7 French, d'obturateur, du filtre **Recovery**, d'un tube de stockage avec orifice pour perfusion de solution saline et d'un système à poussoir. Le filtre **Recovery** est conditionné préchargé à l'intérieur du tube de stockage pour mise en place.

Figure A. Système de filtre Recovery



A. CANULE D'INTRODUCTION
B. TUBE DE STOCKAGE DU FILTRE
C. PERFUSEUR AVEC COUTTE À GOUTTE DE SOLUTION SALINE
D. ORIFICE LATÉRAL
E. ADAPTATEUR MODULAIRE DE TOUHY-BORST
F. FIL DE POUSSOIR EN NITINOL
G. POIGNÉE DU FIL DU POUSSOIR

IMPORTANT : Lisez attentivement les instructions avant d'utiliser le filtre Recovery.

C. Indications d'emploi

Le système de filtre **Recovery** est indiqué dans la prévention des récidives d'embolie pulmonaire par sa mise en place permanente dans la veine cave, dans les situations suivantes :

- Embolie pulmonaire chronique en cas de contre-indication des anticoagulants.
- Échec des traitements anticoagulants ou syndrome thrombo-embolique.
- Traitement en urgence à la suite d'une embolie pulmonaire massive, lorsque les avantages attendus des traitements ont vasculaires sont connus.
- Récidive d'embolie pulmonaire chronique lorsque le traitement anticoagulant a échoué ou est contre-indiqué.
- Le filtre **Recovery** peut être retiré conformément aux instructions fournies ci-dessous dans la Section intitulée : Procédure optionnelle pour retrait du filtre.

D. Contre-indications

ATTENTION : Si le diamètre corrigé de la veine cave inférieure (VCI) dépasse 28 mm, le filtre ne doit pas être introduit dans la VCI.

Le filtre Recovery ne doit pas être implanté chez les patients suivants :

- Patients présentant un risque radioscopique disqualifiant de mise en danger de vie ou fatale. Les risques et avantages doivent être soigneusement évalués.
- Patients présentant un diamètre de la veine cave supérieur à 28 mm
- Patients à risque d'embolie spinale.

E. Mises en garde

Implantation du filtre Recovery

1. Le filtre **Recovery** pour voir été préchargé dans le tube de stockage et il est destiné à un usage unique. Ne déployez pas le filtre avant sa mise en position correcte dans la veine cave (VCI). Le filtre **Recovery** ne pourrait être rechargé sans risque dans le tube de stockage.
2. La mise en place du filtre **Recovery** au travers de la gaine de l'introducteur pelvien uniquement l'anxiété. La rétraction du fil du poussoir pendant la mise en place risquerait d'entraîner un désancrement du filtre, le croisement des pieds ou des bras du filtre, et pourrait empêcher toute progression supplémentaire du filtre à l'intérieur de la gaine.
3. Le système de filtre **Recovery** est conçu uniquement pour des voies d'abord fémorales. N'employez jamais le filtre **Recovery** et le système de mise en place par des voies d'abord supérieures (veine jugulaire, subclavière ou brachiale) car cela risquerait une mauvaise rétraction du filtre **Recovery** dans la veine cave inférieure.
4. En cas de résistance excessive d'une veine rencontrée au cours de la mise en place, ne tentez pas de déployer le filtre au moyen de cet exemplaire. Tentez la mise en place du filtre par un autre site. Un élargissement de petite taille peut être nécessaire pour le fil-guide et l'introducteur.
5. Utilisez uniquement le système de retrait **Recovery Cone** pour retirer le filtre **Recovery**. Ne le déployez jamais un filtre retiré.
6. Ne faites jamais progresser le fil-guide ou la gaine de l'introducteur pelvien et ne déployez jamais le filtre sans guidage fluoroscopique.

Retrait du filtre Recovery

1. N'essayez pas de retirer le filtre **Recovery** si une quantité importante de thrombus est coincée dans le filtre ou si l'extrémité du filtre est prise dans la paroi de la veine cave.
2. Utilisez uniquement le système de retrait Bard **Recovery Cone** (vendu séparément) pour récupérer le filtre **Recovery**. L'utilisation d'autres dispositifs augmente des embolies pulmonaires récurrentes.

F. Précautions

Implantation du filtre Recovery

1. Le filtre doit être placé en position autrale chez les femmes enceintes et celles en âge de procréer.
2. La variabilité anatomique peut compliquer l'introduction et le déploiement du filtre. Lisez attentivement ce mode d'emploi afin de réduire le temps d'introduction et le risque de problèmes.
3. Déformations radiologiques : Il est important de faire preuve de prudence lorsque l'on envisage de retirer le filtre **Recovery** à l'aide du système de retrait **Recovery Cone** chez les patients qui présentent d'importantes déformations radiologiques de type cyphoscoliose. En effet, la veine cave inférieure peut suivre globalement ces déformations anatomiques. La retrait percutané du filtre peut alors nécessiter l'utilisation de techniques avancées.

G. Complications possibles

- Migration du filtre. Celle-ci peut être causée par la mise en place dans une veine cave de diamètre excessif dépassant 28 mm ou si des techniques correctes d'ancrage ne sont pas employées.
- Perforation de la paroi de la veine cave. Celle-ci peut se produire si une technique correcte d'introduction n'est pas employée.
- Occlusion de la veine cave. La probabilité de ce risque n'étant est alors exposée par rapport aux bénéfices attendus chez un patient présentant une embolie pulmonaire vérifiée ou probable sans traitement.

H. Équipement requis

Le matériel suivant est requis :

Un filtre **Recovery** et système de mise en place contenant :

- Un ensemble gaine d'introducteur I.D. 7 French de 40 cm et dilateur
- Un tube de stockage avec filtre **Recovery** préchargé et système de mise en place à poussoir
- Un fil-guide 0,038 pouces à extrémité en J de 3 mm, de 110 cm de long au moins
- Une seringue d'introduction de calibre 18 G
- Solution saline
- Accord de tubulure stérile pour le goutte à goutte ou la perfusion de solution saline
- Tous les matériels de base de pontion veineuse : scalpel, lame n° 11, anesthésique local, champs stériles, etc.
- Un kit d'entrée comprenant un fil-guide 0,038 pouces à extrémité en J de 3 mm, une aiguille d'introduction, un scalpel n° 11 et une seringue de 10 ml est disponible auprès de C. R. Bard, numéro de catalogue 00401.

Si le médecin choisit le retrait percutané du filtre **Recovery**, le système de retrait **Recovery Cone** est disponible auprès de C. R. Bard, Inc.

I. Mode d'emploi

Insertion de la canule d'introduction en 7 French et préhospitalière pelvienne

1. Choisissez une voie d'accès veineuse fémorale adéquate, sur le côté droit ou gauche, selon la compétence ou l'anatomie du patient, les préférences de l'opérateur ou, l'emplacement de la thrombose veineuse.
2. Préparez, recouvrez de champs stériles et anesthésiez le site de ponction artérielle selon les méthodes habituelles.
3. Choisissez et ouvrez l'emballage du système d'introduction **Recovery Cone**. Ouvrez l'emballage du kit.
4. Entaillez la peau avec une lame n° 11 et effectuez une ponction veineuse avec une aiguille d'introduction de calibre 18 G.
5. Introduisez le fil-guide à extrémité en J de 3 mm dans l'extrémité distale de la veine cave ou la veine iliaque.

REMARQUE : En cas de résistance ressentie pendant une procédure d'introduction fémorale, retirez le fil-guide et vérifiez la perméabilité de la veine par examen radioscopique à l'aide d'une petite injection de produit de contraste. En cas de mise en évidence d'un thrombus important, retirez l'aiguille de ponction veineuse et essayez la veine du côté opposé. Un thrombus de petite taille peut être contourné par le fil-guide et l'introducteur.

6. Retirez l'aiguille de ponction veineuse en suivant le fil-guide à extrémité en J. Introduisez la canule d'introduction 7 French avec son dilatateur conique le long du fil-guide jusque dans l'extrémité distale de la veine cave ou la veine iliaque.

REMARQUE : La canule d'introduction dispose de marqueurs radio-opaques facilitant la visualisation et le positionnement du filtre avant son déploiement. Les marqueurs radio-opaques sur la canule d'introduction forment un emplacement "cible" dans lequel le filtre doit être positionné juste avant le retrait de la gaine et le déploiement.

7. Retirez le fil-guide et le dilatateur, en laissant la canule d'introduction et son extrémité dans l'extrémité distale de la veine cave ou la veine iliaque. Fixez de manière intermittente à la main ou raccordez la canule à une perfusion goutte-à-goutte constante de solution saline afin de maintenir la perméabilité de la canule intérieure.

REMARQUE : La garde de la canule d'introduction bénéficie d'une conception inédite, il suffit d'effectuer les mouvements de va-et-vient, mais sans exercer une force excessive qui risquerait de provoquer la rupture de la garde.

8 Effectuez une scintigraphie standard de la veine cave inférieure (en général 30 ml de produit de contraste à 15 mg/ml). Contrôlez la présence éventuelle de tout thrombus dans la veine cave, tout anomalie congénitale et la position des veines rénales. Sélectionnez le niveau optimal pour la mise en place du filtre et mesurez le diamètre de la VCI, en tenant compte du grossissement (généralement 20 pour cent).

9 Avancez la canule d'introduction jusqu'au niveau choisi sous contrôle fluoroscopique. Le fil guide et le dilateur doivent être retirés afin de faciliter cette opération. En cas d'introduction femorale, l'extrémité de la canule d'introduction doit se situer 1 cm sous la veine rénale la plus basse.

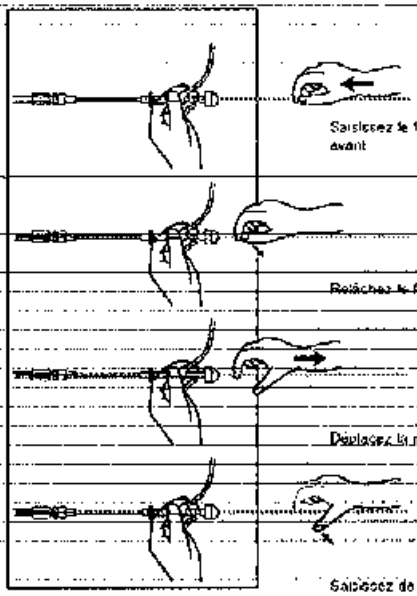
10 Libérez le filtre et le système de mise en place du fil guide.

11 Retirez une poche de 500 ml de solution saline à l'orifice latéral de l'adaptateur en Y à l'aide d'un perfuseur à goutte-à-goutte standard. Laissez la perfusion de solution saline s'écouler à travers le filtre dans le tube de stockage pendant 5 secondes afin d'assurer une purge adéquate du système de mise en place et du filtre. Réglez le perfuseur afin d'obtenir une vitesse rapide de perfusion. Fermez la valve de l'adaptateur de Touhy-Borst afin d'empêcher le reflux de solution saline et veillez à ce que le fil-poussoir puisse progresser sans entrave.

REMARQUE : Il est très important de maintenir la perméabilité de la canule d'introduction grâce à la purge de solution saline, afin que le segment rétracté qui maintient en place correctement les pieds du filtre ne soit pas abîmé. Cela interférerait avec le déploiement du filtre.

12 Fixez l'extrémité libre du tube de stockage du filtre directement sur la canule d'introduction déjà dans la veine, en laissant la perfusion de solution saline s'écouler dans la VCI pendant quelques secondes. La canule d'introduction et le système de mise en place du filtre doivent être alignés afin de minimiser les frottements.

Progression du filtre, illustration



13 Faites progresser le filtre en avançant le fil du poussoir en métal dans la canule d'introduction. Le filtre progressera à chaque mouvement vers l'avant du fil du poussoir (Figures B-E). Ne tirez pas le fil du poussoir en arrière, faites-le uniquement progresser vers l'avant. Afin de faciliter le travail de l'opérateur, ainsi que la manipulation et la progression du fil du poussoir en métal, le fil du poussoir peut effectuer une boucle sans entraîner aucune conduit du matériau en métal.

14 Poursuivez le mouvement vers l'avant du fil du poussoir jusqu'à ce que l'extrémité du fil-guide le marqueur radio-opaque à l'extrémité distale de la canule d'introduction. À ce stade la poignée du fil du poussoir doit se situer en position adjacente à l'adaptateur en Y.

Libération/déploiement du filtre

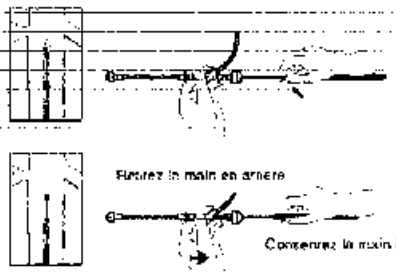
15 Mettez le filtre en place en suivant les instructions ci-dessous.

Figure F: Maintenez fermement la poignée du fil du poussoir

Figure F-1: Vue à position dans la canule d'introduction après les marqueurs radio-opaques avant le déploiement dans la VCI

REMARQUE : Ne mettez pas le filtre en place en l'entonçant au delà de l'extrémité de la canule d'introduction. Au lieu de cela, retirez la canule d'introduction, et ainsi la gaine recouvrant le filtre stationnaire, comme décrit ci-dessous.

Libération du filtre, illustration



Libérez à présent le filtre dans la VCI en retirant comme suit la gaine qui le recouvre :

Positionnez l'extrémité du filtre 1 cm sous la veine rénale la plus basse.

Figure G : Une main étant maintenue en position stationnaire, l'autre main retire entièrement l'adaptateur en Y et l'ensemble du tube de stockage par-dessus la poignée, découvrant et libérant ainsi le filtre.

Figure G-1: Retrait de la gaine recouvrant le filtre dans la VCI

Figure H: La position des mains au début du processus de retrait de la gaine

Figure H-1: Le filtre déployé dans la VCI.

16 Retirez à présent le fil du poussoir dans le tube de stockage en maintenant fermement l'adaptateur en Y, le tube de stockage et l'ensemble de la canule d'introduction en place et en tirant le fil du poussoir en arrière.

17 Replacez la vis perpendiculaire de solution saline sur la perfusion goutte-à-goutte considérée afin de maintenir la perméabilité de la canule d'introduction.

Scintigraphie de suivi de la veine cave

18 Une scintigraphie de suivi de la veine cave peut être réalisée après le retrait de la canule d'introduction dans la veine hépatique (en général 30 ml de produit de contraste à 15 mg/ml).

19 Retirez la canule d'introduction et appliquez une compression standard sur le site de ponction, selon la méthode habituelle afin d'assurer l'hémostase.

PROCEDURE OPTIONNELLE POUR RETRAIT DU FILTRE

Retrait du filtre Recovery

ATTENTION : Il est fortement recommandé que le retrait du filtre Recovery soit effectué uniquement à l'aide du Recovery Cone.

Équipement requis

Le matériel suivant est requis :

- Un système de mise *Recovery Cone* comprenant :
  - Un ensemble gaine de mise en place I.D. 10 French de 75 cm et dilateur
  - Un adaptateur en Y avec *Recovery Cone* et système de mise en place à pousser
- Un fil guide à bout droit à extrémité en J de 3 mm de rayon de courbure
- Une aiguille d'introduction de calibre 18 G
- Dilateur 12 French
- Solution saline
- Flacon de 5 ml rempli de produit de contraste pour la perfusion de solution saline
- Tous les matériaux de base de procédure standard, scalpel, sonde n° 11, ciseaux, pinces, champs stériles, etc.

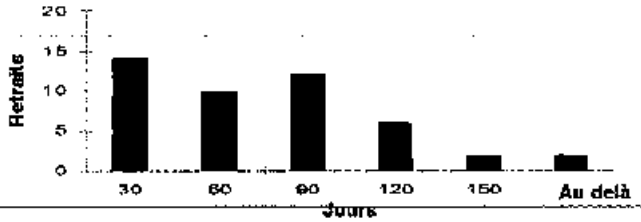
Données cliniques

Le filtre *Recovery* a été utilisé au Canada par un même investigateur et deux de ses collègues dans six hôpitaux régionaux de soins, chez 52 patients conformément au règlement d'accès spécial.

Bien qu'un unique patient ne soit inclus en vue du dépôt, le retrait a été pratiqué par des médecins assistés par des personnels de soutien et des équipements d'imagerie classiques.

Sur les 52 filtres implantés, un total de 46 ont été récupérés. Sept filtres en place et 4 patients n'ont donc pas vu les filtres être retirés pour des raisons non liées à la mise en place du filtre ou à son retrait (anxiété, crainte, polyarthrite, appendicite pulmonaire et hémorragie cérébro-vasculaire). Le temps écoulé avant le retrait était compris entre 1 et 161 jours, avec une moyenne de 60 jours (voir histogramme).

Temps écoulé avant le retrait



Le suivi après le retrait a duré en moyenne 325 jours (entre 1 et 861 jours). La plupart (n=40) des filtres ont été récupérés via la veine jugulaire interne droite, mais certains ont été retirés via la veine jugulaire interne gauche (n=1) et une veine saphène (n=1). Un filtre a été retiré par opération chirurgicale lors de l'opération d'un cancer qui empiétait sur le filtre. Les deux méthodes décrites dans le mode d'emploi ont été utilisées pour récupérer le filtre dans tous les cas, à l'exception de 4 cas où une gaine plus large a été utilisée ou une radioscopie à rayons cathodiques a été réalisée au lieu d'utiliser le système de retrait *Recovery Cone*. Un cas d'embolie pulmonaire asymptomatique a été noté avec la gaine de plus grand diamètre.

Le seul autre événement indésirable signalé est la rupture d'un bras et d'un crochet du filtre. Ce filtre a été placé sous le rein, au niveau L1-L2, chez une femme enceinte pendant le troisième trimestre de grossesse. La rupture a été attribuée au stress de la contraction et au placement sous-rénal, ce qui a probablement entraîné une abrasion importante et une accumulation de caillot dans le bassinet des veinules. Le filtre a été récupéré sans le crochet.

Tableau récapitulatif des données cliniques	
Filtres (Recovery) implantés	56
Retraits perdurance du filtre	45
Retraits chirurgicaux du filtre	1 (concomitant avec la résection tumorale)
Age du patient	5-69 ans (52 ans en moyenne)
Raison de la pose du filtre	
Contre-indication à l'anticoagulation	30
Complications associées à l'anticoagulation	19
Échec de l'anticoagulation	3
Prophylaxie	7
Temps écoulé avant le retrait	1-161 jours (50 jours en moyenne)
Suivi après le retrait	1-911 jours (325 jours en moyenne)
Complications liées au retrait du filtre	
Perforation	1
Rupture du crochet à la suite des stress liés au travail du cœur/rapprochement et position anormale	1
Embolie pulmonaire asymptomatique après le retrait	1

Procédure

Insertion de la canule d'introduction

1. Choisissez une voie d'accès veineuse jugulaire adaptée sur le côté droit ou gauche selon la conformité ou l'anatomie du patient, les préférences de l'opérateur ou l'emplacement de la thrombose veineuse.
2. Préparez, recouvrez de champs stériles et anesthésiez le site de ponction, comme selon les méthodes habituelles.
3. Choisissez et ouvrez l'emballage du système d'introduction Recovery Cone. Ouvrez l'emballage (12 Fr).
4. Installez la pièce avec une lame n° 11 et effectuez une ponction veineuse avec une aiguille de pénétration de calibre 18G.
5. Insérez le fil guide en faites progresser lentement vers l'emplacement du filtre Recovery au niveau de son retrait.
6. Retirez l'aiguille de ponction veineuse en suivant le fil guide.
7. Prédilatez le vaisseau objet de l'intervention à l'aide d'un dilatateur 12 French.
8. Introduisez la canule d'introduction 10 French avec son dilatateur conique le long du fil guide jusque dans la veine.

REMARQUE : Le système d'introduction dispose d'un marqueur radio-opaque à l'extrémité distale de sa gaine afin de faciliter la visualisation.

9. Retirez le fil guide et le dilatateur, en laissant la gaine d'introduction avec l'embout à l'emplacement approprié. Prenez des mesures supplémentaires au moyen de la canule à une personne gauche à gauche conseillée de surveiller votre site de ponction la perméabilité de la gaine d'introduction.
10. Effectuez une cavographie standard de la veine cave inférieure (en général 30 ml de milieu de contraste à 15 ml/s) Recherchez d'éventuels thrombus dans le filtre. Si des thrombus importants se sont formés dans le filtre Recovery, ne le retirez pas.

Insertion et mise en place du Recovery Cone

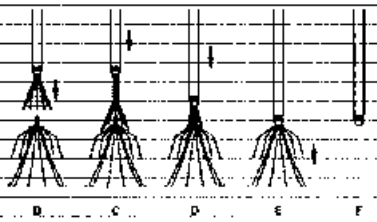
11. Enfilez le Recovery Cone et le système à pousser du fil B.
12. Retirez la languette centrale du système à pousser et humidifiez le cône avec une solution saline (à préférence une solution héparinée).
13. Retirez doucement le cône dans l'adaptateur en Y situé de la capte.

REMARQUE : Le cône doit être entièrement rétracté dans l'adaptateur en Y avant de retirer le système à la gaine d'introduction afin d'assurer la mise en place correcte du cône dans la gaine.

14. Retirez une poche de 500 ml de solution saline stérile (chauffée à température ambiante) et branchez la tubulure de l'adaptateur en Y. Laissez couler la solution saline autour du cône de retrait dans l'adaptateur en Y pendant 5 secondes. Fermez la valve de l'adaptateur de Touhy-Borst afin de maintenir le cône de retrait dans la solution saline vers le duvet, en retirant à ce que la tige du pousseur puisse progresser sans entraves.
15. Raccordez l'extrémité mâle de l'adaptateur en Y, cône abaissé, directement sur la canule d'introduction. La canule d'introduction et le système de mise en place du filtre doivent être alignés afin de minimiser les frottements.
16. Faites progresser le cône en avançant la tige du pousseur dans la canule d'introduction, le cône progressera à chaque mouvement vers l'avant de la tige du poussoir.
17. Poursuivez le mouvement vers l'avant de la tige du poussoir jusqu'à ce que le cône atteigne le marqueur radio-opaque à l'extrémité distale de la canule d'introduction. Retirez la gaine pour exposer le cône en stabilisant la tige et en rétractant la canule

Capture du filtre Recovery

Retrait du filtre, illustration



18. Le capture du filtre Recovery est illustrée dans les figures B à F.

Figure B: Une fois le cône ouvert au-dessus du filtre, avancez le cône et la gaine de l'introducteur en maintenant en place la canule d'introduction et en avançant la tige du poussoir. Il est recommandé d'obtenir une image fluoroscopique antéro-postérieure afin de vérifier le positionnement du cône au-dessus du filtre.

Figure C: Retirez le cône sur l'extrémité du filtre en avançant la canule d'introduction sur le cône tout en maintenant la tige du poussoir immobile.

Figure D: Continuez à faire avancer la canule d'introduction sur le cône jusqu'à ce que ce dernier se trouve à l'intérieur de la canule.

Figure E: Le cône étant abaissé sur le filtre, retirez ce dernier en stabilisant le canule d'introduction et en rétractant la tige du poussoir en mouvements réguliers et contrôlés.

Figure F. Le filtre est rétracté dans la canule.

Scintigraphie de suivi de la veine cave

19. Une scintigraphie de suivi de la veine cave peut être réalisée après le retrait de la canule d'introduction (en général 30 ml de produit de contraste à 15 ml/s).

20. Retirez la canule d'introduction et appliquez une compression standard sur le site de ponction selon la méthode habituelle afin d'obtenir l'hémostase.

Fil guide - Technique assistée

Étant donnée la variabilité anatomique de la position du filtre Recovery, les techniques par fil guide peuvent être classées utilisation du fil guide.

S'il est difficile d'avancer le cône le long de l'extrémité du filtre Recovery, il est possible d'utiliser un fil guide afin de faciliter cette opération.

Retirez le guide en maintenant en place le système d'introduction. Retirez l'aiguille de ponction. Insérez le fil guide dans la gaine d'introduction jusqu'à ce que la pointe du fil guide soit visible à l'extrémité distale de la gaine d'introduction. Avancez le fil guide jusqu'à ce que la pointe du fil guide soit visible à l'extrémité distale de la gaine d'introduction. Retirez la gaine d'introduction tout en maintenant en place le fil guide. Insérez le système à pousser du fil B sur le fil guide et faites progresser le cône jusqu'à ce qu'il soit visible à l'extrémité distale de la gaine d'introduction. Retirez le fil guide et le système à pousser du fil B. Retirez la gaine d'introduction et appliquez une compression standard sur le site de ponction selon la méthode habituelle afin d'obtenir l'hémostase.

Lorsque vous avez constaté que le fil guide est en contact avec l'extrémité du filtre ou proche de cette position, avancez le cône sur le fil guide vers l'extrémité du filtre.

Avancez la gaine de l'introducteur afin d'engager légèrement le cône sur l'extrémité du filtre. Retirez le fil guide dans la tige du poussoir.

Continuez à faire avancer le cône jusqu'à l'étape 16.

J. Conditionnement

Chaque filtre Recovery est fourni préchargé dans son tube de stockage. Tous les filtres Recovery sont stérilisés et apyrogènes sauf si l'emballage a été endommagé ou ouvert, et sont prêts à l'emploi à l'usage unique. Le tube de stockage et le système de mise en place sont préassemblés. Si le filtre est déchargé par inadvertance, ne le remettez pas dans le récipient ou de la recharger.

Remarque : Après insertion, les accessoires du filtre Recovery et les fournitures d'accompagnement peuvent présenter un risque biologique potentiel. Manipulez-les et éliminez-les conformément aux pratiques médicales validées et aux réglementations locales étatiques et fédérales applicables.

Le filtre Recovery doit être conservé dans un endroit sec et frais (température ambiante).

K. Garantie

Bard garantit à l'acheteur d'origine que ce produit est exempt de défauts matériels et de main-d'œuvre pendant une période d'un an à compter de la date d'achat initial. La responsabilité liée à la garantie de ce produit sera limitée à la réparation ou au remplacement du produit défectueux, à l'entière discrétion de Bard, ou pourra également donner lieu au remboursement du prix d'achat payé. La responsabilité de Bard, en vertu de cette garantie limitée, ne s'étendra pas à un emploi abusif de ce produit ou à une nouvelle réutilisation d'une utilisation normale.

DANS LES LIMITES AUTORISÉES PAR LES LOIS EN VIGUEUR, CETTE GARANTIE LIMITÉE REMPLACE TOUTES LES AUTRES GARANTIES, EXPRESSES OU IMPLICITES, Y COMPRIS, MAIS SANS LIMITATION À, TOUTE GARANTIE IMPLICITE DE QUALITÉ MARCHANDE OU D'ADÉQUATION À UN USAGE PARTICULIER. BARD NE SAURAIT EN AUCUN CAS ÊTRE TENU RESPONSABLE DES DOMMAGES ACCESSOIRES OU INDIRECTS RÉSULTANT DE VOTRE MANIPULATION OU UTILISATION DE CE PRODUIT.

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Date d'étiquetage : 12-03

Si 5 ans se sont écoulés entre cette date et l'utilisation du produit, contactez C. R. Bard Inc. pour savoir si des informations supplémentaires sur le produit sont disponibles.

Références :

1. ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2006 (Res 12, Effective 01/01/07)

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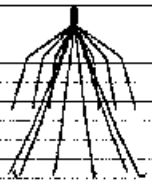
Recovery® Filter System zur Anwendung in der Vena Cava



DEUTSCH

Gebrauchsinformation

Achtung: Nach US-amerikanischem Bundesgesetz darf dieses Produkt nur an einen Arzt oder auf Bestellung eines Arztes verkauft werden.

A. Allgemeine Informationen

Der *Recovery* Filter gehört zu einer neuen Generation von Vena-cava-Filtervorrichtungen, die Lungenembolien verhindern sollen. Das entgegen Design ermöglicht es das *Recovery* Filters gezielt in den Blutgefäßen und gestalten die perkutane Platzierung durch ein angiographisches Standard-Einführbesteck mit einem Innendurchmesser von 7 French mit minimalen Problemen am Eingriffsort. Die Platzierung erfolgt schnell und einfach.

Das Konzept des Set für das Vena-cava durch einen 45 cm langen Einführungskatheter bei einem Innendurchmesser von 7 French erlaubt Verwendung eines flexiblen Schiebdrahtes aus Nitinol geeignet. Ein Polster am Drahtende schützt sich auf die Filterspitze und ein eingebettes Segment hat die Filterscheibe und zentriert sie in der richtigen Stellung. Diese Bauteile führen den Filter am Schiebdraht, während dieser den Filter mit der Spitze zuerst zum distalen Ende des Katheters, entweder in der unteren Hohlvene, verschiebt. Wenn die Spitze des Filters sich der Spitze des Einführungskatheters nähert, liegt sie zwischen den nitinolbeschichteten Markierungen auf dem Einführungskatheter. Der Einführungskatheter und das Schiebdrahtbesteck werden dann als das Handstück des Schiebdrahts zurückgezogen, und der Filter aus dem Einführbesteck zu lösen und in freizugeben, damit er seine vorbestimmte Gestalt annehmen kann. Mit dem Zentriersystem kann der *Recovery* Filter mit zentrierter Filterspitze abgelegt werden, so dass die Schenkel sich nicht kreuzen.

Der *Recovery* Filter ist als Permanentfilter bestimmt. Sollte entsprechende Maßnahmen erforderlich kann der *Recovery* Filter nach Implantation gemäß den Anweisungen unter "Optionales Filter-Bergungsverfahren" geborgen werden. Durch die elastischen Filter kann der *Recovery* Filter stark biegen und Manöver widerstehen, ohne bei der perkutanen Bergung des Filters Haken zu stecken verformen. (Genaue Anweisungen zur Bergung siehe unter „Optionales Filter-Bergungsverfahren").

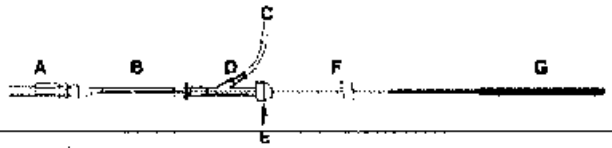
Achtung: Der implantierte *Recovery* Filter ist MR-sicher und darf nicht den Betrieb eine MR-Vorrichtung oder -Feld von der beeinflussen.

B. Produktbeschreibung

Das *Recovery* Filter System besteht aus Filter und Schiebenführsystem. Der *Recovery* Filter besteht aus zwölf Nitinol-Streben mit Formgedächtnis, die von einer zentralen Nabe ausgehen. Diese zwölf Streben bilden zwei Filterebenen für Einbau die Schenkel und die unteren Filterebene und die Arme die obere Filterebene. Der *Recovery* Filter ist für die Verwendung in einer Vena cava mit einem Durchmesser bis zu 28 mm bestimmt.

Das *Recovery* Filter Schiebefilter-System ist in Abbildung A gezeigt. Das Schiebenführsystem besteht aus einem Einführungsbesteck mit einem Innendurchmesser von 7 French und einem Dilator, dem *Recovery* Filter, einem Aufbewahrungsteile mit Kochsalzlösung für physiologische Kochsalzlösung und einem Schiebsystem. Der *Recovery* Filter ist in der Verpackung bereits in dem Abzug-Aufbewahrungsbehälter getrennt.

Abbildung A. *Recovery* Filter System



A EINFÜHRUNGSKATHETER
B FILTER-AUFBEWAHRUNGSBEHÄLTER
C VERSCHLUSS FÜR PHYSIOLOGISCHE KOCHSALZLÖSUNG
D SPITZENÖFFNUNG
E VERSTELLBARER TOUHY-BORST-ADAPTER
F NITINOL-SCHIEBDRAHT
G HANDSTÜCK DES SCHIEBDRAHTS

WICHTIG: Lesen Sie die Gebrauchsinformation sorgfältig, bevor Sie den *Recovery* Filter verwenden.

C. Indikationen

Das *Recovery* Filter System ist für die Prävention von rezidivierenden Lungenembolien durch perkutane Platzierung in der Vena cava in folgenden Situationen vorgesehen:

- Patienten, die eine Antikoagulationstherapie nicht vertragen
- Versagen der gerinnungshemmenden Therapie bei thromboembolischer Erkrankung
- Patienten, die nach massiver Lungenembolie, wenn die erwartete Vorteile einer konventionellen Therapie vorgesehen sind
- Chronische, rekurrente Lungenembolie, wenn die gerinnungshemmende Therapie versagt hat oder kontraindiziert ist.
- Der *Recovery* Filter kann gemäß den Anweisungen im Abschnitt "Optionales Filter-Bergungsverfahren" geborgen werden.

D. Kontraindikationen

ACHTUNG: Wenn der Durchmesser der Vena cava inferior (IVC) nach Korrektur größer als 28 mm ist, darf der Filter nicht in die IVC eingeführt werden.

Der *Recovery* Filter darf in folgenden Fällen nicht implantiert werden:

Schwangere Patientinnen, wenn die Thrombolyse den Fötus gefährden kann. Die Risiken sind sorgfältig gegen die Vorteile abzuwägen.

Patienten mit Vena-cava-Durchmesser über 28 mm.

Patienten mit Risiko für septische Embolie.

E. Warnhinweise

Implantation des *Recovery* Filters

1. Der *Recovery* Filter Vena cava Filter ist bereits zur Aufbewahrungsteile geladen worden ist für den einmaligen Gebrauch bestimmt. Der *Recovery* Filter darf vor der richtigen Positionierung in der Vena cava inferior (IVC) nicht abgelegt werden, und er nicht gelöscht werden in das Aufbewahrungsteile geladen werden kann.
2. Der *Recovery* Filter darf durch das Einführungsbesteck nur durch Vorschieben eingesetzt werden. Zurückziehen des Schiebdrahts beim Einsatz könnte dazu führen, dass der Filter sich in der Filterscheibe oder -arme sich brechen und es könnte vorkommen, dass der Filter unter das Einführungsbesteck eingezogen werden kann.
3. Das *Recovery* Filter System darf nur über den Femoralis-Zugang eingeführt werden. Der *Recovery* Filter und das Schiebenführsystem dürfen niemals superior (jugularis, subclavia oder antecubitalis) eingeführt werden, weil dies zu falscher Orientierung des *Recovery* Filters in der Vena cava inferior führt.
4. Bei vorliegen größer Thrombusmengen im ersten Einführungsbesteck nicht versuchen, den Filter durch die Thromben hindurch einzuführen. Versuchen Sie den Filter durch eine andere Stelle einzuführen. Bei kleiner Thrombus kann mit dem Führungsdraht und das Einführungsbesteck umgangen werden.
5. Verwenden Sie zum Bergen des *Recovery* Filters nur das *Recovery Cone* Bergungssystem. Ein gebrauchter Filter darf niemals erneut eingeführt werden.
6. Führungsdraht und Einführungsbesteck Dilator dürfen niemals ohne fluoroskopische Kontrolle vorgeschoben werden. Auch der Filter darf niemals ohne fluoroskopische Kontrolle eingesetzt werden.

Bergung des *Recovery* Filters

1. Versuchen Sie niemals den *Recovery* Filter zu bergen wenn signifikante Thrombusmengen im Filter zurückgehalten werden oder wenn die Filterspitze in die Wand der Vena cava eingebettet ist.
2. Verwenden Sie zum Bergen des *Recovery* Filters ausschließlich das Bard *Recovery Cone* Bergungssystem. Jegliche Verwendung anderer Produkte hat zu schwerwiegender Lungenembolien geführt.

F. Vorsichtsmaßnahmen

Implantation des *Recovery* Filters

1. Der Filter sollte bei Schwangeren und Frauen im gebärfähigen Alter nur eingesetzt werden, wenn der potentielle Nutzen eindeutig die potentiellen Risiken überwiegt.
2. Anatomische Unterschiede können die Einführung und den Einsatz des *Recovery Cone* Systems komplizieren. Bei sorgfältiger Beachtung dieser Gebrauchsanweisungen kann die Einführung rascher verläuft und die Wahrscheinlichkeit von Komplikationen reduziert werden.
3. Wirbelsäulendeformationen: Wird die Implantation des *Recovery* Filters bei Patienten mit signifikanten kyphotischen Wirbelsäulendeformationen erwogen, muss besonders vorsichtig vorgegangen werden. Da die Vena cava infolge der Grundform solcher anatomischer Deformationen folgen kann. Es kann sein, dass sich der Filter in seltenen Fällen nicht in der Anwendung gemäß den Technik-Tipps lösen lässt.

G. Mögliche Komplikationen

- Migration des Filters. Dies kann durch Platzierung in einer zu großen Vena cava mit einem Durchmesser über 28 mm verursacht werden, oder wenn nicht die richtigen Verankerungsschritte verwendet werden.
- Perforation der Vena-cava-Wand. Dies kann passieren wenn nicht die richtige Einführungstechnik verwendet wird.
- Cava-Okklusion. Das Risiko für diese Komplikation sollte bei einem Patienten mit Lungenembolie oder bei dem eine Lungenembolie eine Intervention wahrscheinlich ist, gegen das Risiko-Nutzen-Verhältnis abgewogen werden.

H. Erforderliche Materialien

Es werden die nachstehender Materialien benötigt:

Ein *Recovery* Filter und Schiebenführsystem bestehend aus:

- Set aus Einführbesteck, 45 cm lang, 7 French Innendurchmesser, und Dilatator
- 1 Aufbewahrungsteil mit geladenem *Recovery* Filter und Schiebenführsystem
- 0,035" Führungsdraht mit 3 mm J-Spitze, 150 cm lang oder länger
- 18 Gauge Zugangsnadel
- Kochsalzlösung
- Sterile Verlängerungsschläuche für Kochsalzlösungsbeutel oder -infusion
- Alle notwendigen Grundmaterialien zur Venenpunktion: Skalpell, Nr. 11 Klinge, lokale Anästhetika, Tücher usw.
- Einführungsbesteck bestehend aus 0,038" 3 cm Führungsdraht mit J-Spitze, Zugangsnadel, Nr. 11 Klinge und 10 ml Spritze ist von C. R. Bard erhältlich. Katalognummer 4000E.

Wenn sich der Arzt für die perkutane Bergung des *Recovery* Filters entscheidet, ist das *Recovery Cone* Bergungssystem von C. R. Bard, Inc. erhältlich.

I. Vorgehensweise

Einbringen des 7 French Einführungskatheters und richtige Platzierung:

1. Wählen Sie entsprechend der Größe und Lage des Patienten, der Patient des Arztes oder der Location der Venenkompresse einen geeigneten femoralen Venenzugang auf der rechten oder linken Seite.
2. Nehmen Sie Vorbereitung, Abdeckung sowie Betäubung der Zugangsstelle entsprechend der Routine vor.
3. Wählen und öffnen Sie die Filterpackung. Öffnen Sie das Kit A Packung, welche das Einführungsbesteck enthält.
4. Machen Sie mit einer Nr. 11 Klinge einen Schnitt in die Haut und schneiden Sie mit einer 18 Gauge Nadel einer Venenzugang.
5. Führen Sie den Führungsdraht mit J-Spitze und aktivieren Sie ihn vorsichtig bis in die distale Vena cava oder Rasa vor.

HINWEIS: Wenn beim Einführen über die V. femoralis Widerstand fühlbar ist, ziehen Sie den Führungsdraht zurück und überprüfen Sie die Durchgängigkeit der Vene. Radiologisch mit Injektion einer geringen Menge Kontrastmittels. Bei Vorliegen eines großen Thrombus entfernen Sie die Venenzugangsnadel. Versuchen Sie dann die Vene auf der gegenüberliegenden Seite. Ein kleiner Thrombus kann mit dem Führungsdraht und dem Einführungsbesteck umgangen werden.

6. Entfernen Sie die Venenzugangsnadel über den Führungsdraht mit J-Spitze. Schieben Sie den 7 French Einführungskatheter zusammen mit seinem verfügten Dilatator über den Führungsdraht in die distale Vena cava oder Rasa.

HINWEIS: Zugangsstellen können Durchblutung und Positionierung des Filters vor dem Einsatz beeinflussen.

Einführungskatheter röntgendichte Markierungen. Die röntgendichten Markierungen auf dem Einführungskatheter bieten als „Zielgebiet", zwischen dem der Filter vor dem Lösen aus dem Besteck und dem Einsatz positioniert werden sollte.

7. Entfernen Sie Führungsdraht und Dilatator und belassen den Einführungskatheter mit der Spitze in der oberen Vena cava oder Rasa. Spülen Sie zur Aufrechterhaltung der Durchgängigkeit des Einführungskatheters periodisch von Hand vor allem Sie eine konstante Kochsalzlösung-Tropfinfusion anschließen an.

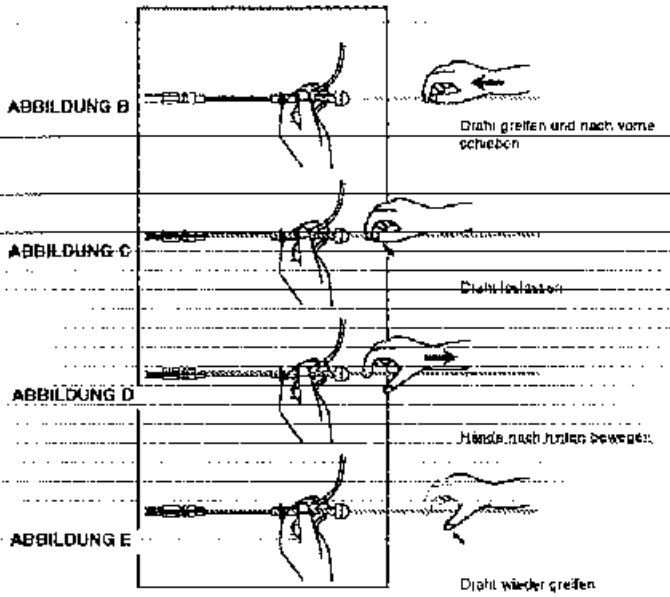
HINWEIS: Der Steril-Protektor des Einführungskatheters weist ein besonderes Innendesign auf. Es muss sorgfältig darauf geachtet werden, dass die Verbindungen fest angezogen werden, aber ohne dabei übermäßige Gewalt anzuwenden, die zum Brechen des Steril-Protektors führen könnte.

1. Positionieren Sie den Standard-Führungsdraht (Kurzschraubteil bei 15 cm) [illegible] Kontrollieren Sie all Thrombus in der V. cava, Position der Nierenvenen und angebrachte Anomalien. Wählen Sie die optimale Höhe für die Filterplatzierung und messen Sie den Durchmesser der IVC mit Kontrast mit Vergrößerung (in der Regel 2, Projekt).
2. Schieben Sie den Einführungskatheter unter fluoroskopischer Kontrolle bis zur gewünschten Höhe. Zur Erleichterung sollten dann wieder der Führungsdraht und der Dilatator eingeführt werden. Für die Einführung des Einführungskatheters durch die V. femoralis sollte auch die Spitze 3 cm unter die, wo sich die Nierenvenen befinden.
3. Nehmen Sie Filter und Schiebedraht heraus aus dem Kit.
4. Schließen Sie einen Standard-Kontrast-Applikator mit Verwendung eines Standard-Trichterverschlusses an den Schaft des Y-Adapters an. Lassen Sie die Kochsalzlösung wieder mit Spülung langsam durch den Filter im Katheterschaft laufen, damit er für die Passage durch den Einführungskatheter bereit wird. Stellen Sie das Infusionsset für eine schnelle Injektion ein. Schließen Sie das Touhy-Borst-Adapterventil, um den Kochsalzlösung zu minimieren, jedoch nicht so fest, dass sich der Schieberschaft nicht mehr verschieben lässt.

HINWEIS: Es ist sehr wichtig, dass die Durchgängigkeit des Einführungskatheters mit der Kochsalzspülung sichergestellt wird, damit das angebrachten Segment, das die Filterschenkel hält und richtig orientiert, nicht mit Gerinnseln bedeckt wird. Dies würde den Filtereinsatz stören.

12. Schließen Sie das freie Ende des Filter-Aufbewahrungsrohrs direkt an den sich bereits in der Vene befindlichen Einführungskatheter an und lassen Sie die Kochsalzlösungsinfusion einige Sekunden lang in die IVC fließen. Der Einführungskatheter und das Filterlagersystem müssen zur Kennzeichnung vor Reibung gereinigt werden.

Vorschieben des Filters, abgebildet



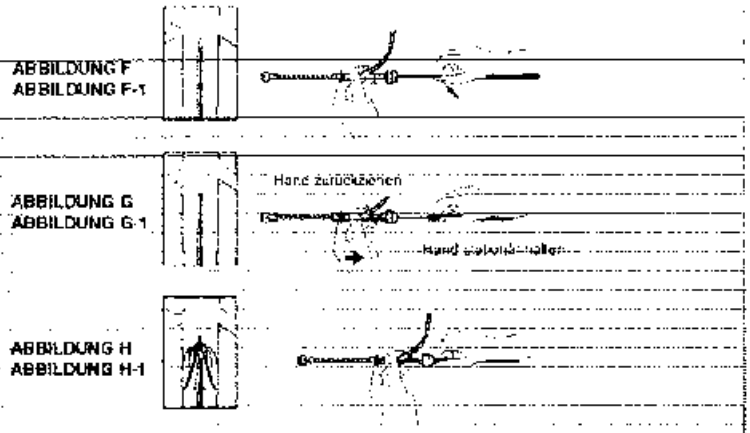
13. Ziehen Sie den Filter durch Vorschieben des Nitinol-Schiebestabs durch den Einführungskatheter, so dass der Filter bei jeder Vorwärtsbewegung des Schiebestabs vorgeschoben wird (Abbildung B-F). Ziehen Sie den Schiebedraht nicht zurück, der Schiebedraht darf nur nach vorne geschoben werden. Für einfachere Handhabung durch die Kurve kann der Nitinol-Schiebedraht zu einer Schlaufe geformt werden, ohne das Nitinol-Material zu knicken. Damit der Schiebedraht leichter gehandhabt und vorgeschoben werden kann.
14. Schieben Sie solange mit dem Schiebedraht nach vorne, bis die Filterspitze die röntgendichte Markierung am distalen Ende des Einführungskatheters erreicht hat. Das Handstück des Schiebestabs sollte sich jetzt neben dem Y-Adapter befinden.

Freigabe/Einsatz des Filters

15. Freigabe und Einsatz des Filters erfolgen wie unten beschrieben:
   Abbildung F: Positionieren des Schiebestabs und halten.
   Abbildung F-1: Filter positionieren im Einführungskatheter zwischen den röntgendichten Markierungen vor Einsetzen in die IVC.

HINWEIS: Beim Einsetzen des Filters darf er nicht über das Ende des Einführungskatheters hinaus geschoben werden. Legen Sie den platzierten Filter frei, indem Sie stattdessen den Einführungskatheter, wie unten beschrieben zurückziehen.

Freigabe des Filters, abgebildet



Geben Sie den Filter jetzt frei, indem Sie ihn in der IVC wie folgt aus dem Einführungskatheter lösen:

Positionieren Sie die Filterspitze 1 cm unter der unteren Nierenvene.

Abbildung G: Halten Sie eine Hand stationär und ziehen Sie mit der anderen Hand den Y-Adapter und das Aufbewahrungsrohr vollständig bis über das Handstück zurück, wodurch der Filter freigesetzt wird.

Abbildung G-1: Freisetzen des Filters in der IVC.

Abbildung H: Die Position der Hände am Ende des Freisetzungsvorgangs.

Abbildung H-1: Der in der IVC eingesetzte Filter.

16. Ziehen Sie den Schiebestab jetzt zurück in das Aufbewahrungsrohr, indem Sie den Y-Adapter, das Aufbewahrungsrohr und den Einführungskatheter gut festhalten und den Schiebestab nach hinten ziehen.
17. Führen Sie mit der gewünschten Kochsalzlösungsspülung oder der [illegible] Trichterkuppe ein, um den Einführungskatheter durchgängig zu halten.

Bild der Vena cava zur Kontrolle

18. Nach dem Zurückziehen des Einführungskatheters in die V. cava kann ein Kontrast-Bild der Vena cava mit Kontrastmittel bei 15 (45) aufgenommen werden.
19. Entfernen Sie den Einführungskatheter und verpragen Sie die Zugangsstelle entsprechend des Patientenvorgehens mit Kompression, um Hämatome zu verhindern.

OPTIONALES FILTER-BERGUNGSVERFAHREN:

Bergung des Recovery Filters

ACHTUNG: Es wird dringend empfohlen, den Recovery Filter nur mit dem Recovery Cone zu bergen.

Erforderliche Materialien

Es werden die nachstehenden Materialien benötigt:

- Ein Recovery Cone Bergungssystem bestehend aus:
  - Set aus 1 Führungsdraht, 75 cm lang, 10 French Innendurchmesser und Dilatator
  - 1 Y-Adapter mit Recovery Cone und Schiebeverschlussteil
- 0,025" Führungsdraht mit 3 mm J-Spitze, 180 cm lang oder länger
- 18 Gauge Zugangsnadel
- 12 French Dilatator
- Kochsalzlösung
- Steriler Verfärbungsgeschlauch für Kochsalzlösung mit Spritze zur Infusion von Kochsalzlösung
- Alle notwendigen Standardmaterialien zur Venenpunktion (Beispiel: Nr. 11 Klinge, sterile Abdeckung, Tücher usw.

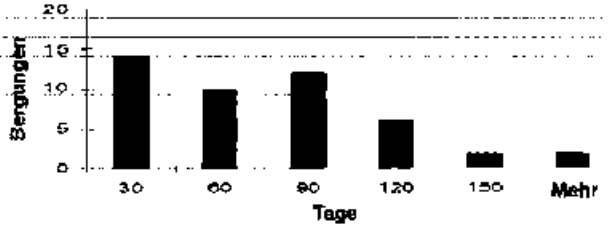
Klinische Erfahrung

In Kanada haben 68 Patienten von einem einzelnen Prüfarzt in Zusammenarbeit mit zwei Kollegen an sechs Krankenhäusern in und um Toronto den Recovery Filter nach den Vorschriften des "Special Access" erhalten.

Im Vereinigten hat sich Aus das Produkt [illegible]. Die Bergung erfolgte jedoch durch die Ärzte mit jeweils anderen Mitarbeitern und anderen beigebrachten Anlagen.

Von den 68 implantierten Filtern wurden insgesamt 40 entfernt, 5 Filter lagen noch und 4 Patienten starben mit implantiertem Filter aus Gründen ohne Zusammenhang mit der Platzierung oder Bergung des Filters (Leukämie, Krebs, Pneumonie und pulmonale Aspiration sowie klinisch plötzlicher Schlaganfall). Die Zeit bis zur Bergung betrug 4 bis 151 Tage, im Durchschnitt 60 Tage (siehe Histogramm).

Zeit bis zur Bergung



Die Nachbeobachtung nach Bergung betrugen Median 325 Tage (Bereich: 1-901 Tage). Die restlichen [illegible] wurden Filter die nicht Vena jugularis interna entfernt am Filter über die linke Vena jugularis interna (n=1) und ein Filter über eine kontralaterale Vena jugularis (n=1). Bei einem Filter erfolgte die Bergung chirurgisch bei einer Tumorpatientin, wo der Tumor auf der Filter drückte. Die Bergung der Filter erfolgte in zehn Fällen nach den zuvor in den Gebrauchsinformationen beschriebenen Methoden, außer dass bei vier Filtern ein größeres Bergefangschlinge zusätzlich das Recovery Cone Bergungssystem gewählt wurde. Die Verwendung des größeren Bergefangschlinge in Fall asymptomatischer Lungenembolie aufgetreten.

Das einzige weitere unerwünschte Ereignis, das berichtet wurde, war ein gebrochener Filterarm und -haken. Dieser Filter war bei einer in dritter Trimester schwangeren Frau mittels Röntgenaufnahme auf die Hülle 3 HLE platziert worden. Es wurde angenommen, dass der Bruch auf Belastungen durch starke Verformung und Einbettung des Hakens in das Knochengewebe der Wirbel bei der Entfernung und der mittleren Platzierung zurückzuführen war. Der Filter wurde ohne Folgen geborgen.

Zusammenfassende Durchführung der klinischen Erfahrung	
Anzahl der implantierten *Recovery* Filter	52
Versuchte Filterbergungen	45
Optimale Filterbergungen	1 (Definition im Protokollabschnitt)
Alter des Patienten	8 89 Jahre (52 Jahre im Durchschnitt)
Gründe für die Filterplatzierung	
Kontraindikation für Antikoagulation	46
Mit Antikoagulation verknüpfte Komplikationen	13
Fehlschlag der Antikoagulation	3
Prophylaxe	2
Zeit bis zur Bergung	1 Tag bis 1629 Tage (Durchschnitt)
Nachbeobachtung nach Bergung	1 901 Tage (325 im Durchschnitt)
Komplikationen bei Filterbergung	
Todesfälle	0
Herzstillstand nach Behandlungen durch Wirbelsäule	
Gehirn sowie die integrierte Fixierung	1
Asymptomatische Lungenembolie nach Bergung	1

Vorgehenshinweise

Einlegen des Einführungsschleiers

1. Wählen Sie entsprechend der Größe oder Konturen des Patienten, der Präferenz des Arztes oder der Lokalisierung der Vena jugularis oder femoralis geeigneten seitlichen Venenzugang auf der rechten oder linken Seite.
2. Nehmen Sie Vorbereitung, Abdeckung sowie Betäubung der Zugangsstelle entsprechend der Routine vor.
3. Mit Messer öffnen Sie die *Recovery* Cone Katheterpackung. Öffnen Sie die Kit A Packung, welche den Einführungsschleier enthält.
4. Drücken Sie sich durch Hr. 11 Klinge neue Schleier in die Kappe und schieben Sie sie über 1,4 cm Nadel einer Venenzugang.
5. Führen Sie den Führungsdraht ein und schieben Sie ihn vorsichtig bis zur Lokalisierung des zu bergenden *Recovery* Filters vor.
6. Entfernen Sie die Venenzugangsnadel über den Führungsdraht.
7. Das als Zugang gewählte Gefäß mit einem 12 French Dilatator vordilatieren.
8. 10 French Einführungsschleier zusammen mit einem verfügbaren Dilatator über den Führungsdraht in die Vene schieben.

HINWEIS: Zugunsten besserer Durchsichtigkeit trägt der Einführungsschleier an seinem Ende eine röntgendichte Markierung.

9. Entfernen Sie Führungsdraht und Dilatator und belassen den Einführungsschleier mit der Spitze in der gewünschten Position. Spülen Sie zur Aufrechterhaltung der Durchgängigkeit des Einführungsschleiers periodisch mit Kochsalz- oder heparinisierter Kochsalzlösung. Verfahren wie Infusion von Katheter ist
10. Erstellen Sie ein Standardbild der Vena cava inferior (gewöhnlich 90 cm Kathetermaß bei 15 Hrsg). Kontrollieren Sie den Filter auf Thromben. Bei signifikanter Thrombenansammlung im Filter darf der *Recovery* Filter nicht geborgen werden.

Einführen und Positionieren des Recovery Cone

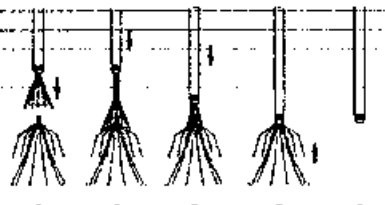
11. Nehmen Sie Cone und Schiebeverschlussteil aus dem Kit B.
12. Spülen Sie das zentrale Lumen des Conekatheters und befeuchten Sie den Cone mit Kochsalzlösung—vorzugsweise mit heparinisierter Kochsalzlösung.
13. Ziehen Sie den Cone langsam in den Y-Adapter damit der Cone sich zusammenzieht.

HINWEIS: Der Cone muss vollständig in den Y-Adapter zurückgezogen sein, bevor das System an den Einführungskatheter angeschlossen wird, da nur so sichergestellt ist, dass der Cone leicht durch den Katheter eingeführt werden kann.

14. Schließen Sie einen 5/0 ml-Behälter oder eine Spritze mit Kochsalzlösung an den Seitenport des Y-Adapters an. Lassen Sie die Kochsalzlösung fließen. 5 Schleifenbindung im Y-Adapter um den Beatmungsschlauch befüllen. Schließen Sie das Tuohy-Borst Adapterventil um den Rückfluss von Kochsalzlösung zur Zuführung zu minimieren, jedoch nicht so fest, dass sich der Schieberschaft nicht mehr frei vorschieben lässt.
15. Schieben Sie das offene Ende des Y-Adapters über den zusammengefalteten Cone und in den Einführungsschleier an. Der Einführungsschleier und das Filterspritzgerät müssen zur Minimierung von Reibung gerade gehalten werden.
16. Schieben Sie den Cone durch Vorschieben des Schieberschafts durch den Einführungsschleier, so dass der Cone die freie Vorschiebebewegung des Schieberschafts vermindert wird.
17. Schieben Sie solange mit dem Schieberschaft nach vorne, bis der Cone die röntgendichte Markierung des distalen Endes des Einführungsschleiers erreicht hat. Entfernen Sie den Cone danach sehr schnell, indem Sie den Schaft stabil halten und den Einführungsschleier zurückziehen.

Erfassen des Recovery Filters

Bergung des Filters, abgebildet



18. Siehe Abbildungen B-F, auf denen das Erfassen des *Recovery* Filters bildlich dargestellt ist.

Abbildung B: Schieben Sie den Cone nochmals so weit vorwärts bis der Filter geöffnet ist. Über die Filterspitze, indem Sie den Einführungsschleier stationär halten und den Schaft vorschieben. Es wird empfohlen, von anterior schräg zu durchqueren, um einen Überspringen zu können, passieren des Cone über den Filterspitze befindet.

Abbildung C: Schieben Sie den Cone über die Filterspitze, indem Sie den Einführungsschleier über den Cone schieben und den Schaft drehen halten.

Abbildung D: Schieben Sie den Einführungsschleier weiter über den Cone vor, bis sich der Cone im Einführungsschleier befindet.

Abbildung E: Bergen Sie den Filter bei über dem Filter zusammengefahrenen Cone, indem Sie den Einführungsschleier und den Schieberschaft in einer glatten, kontinuierlichen Bewegung zurückziehen.

Abbildung F: Der Filter ist in den Einführungsschleier zurückgezogen.

Bild der Vena cava zur Kontrolle

19. Nach dem Zurückziehen des Einführungsschleiers kann ein Kontrolle ein Bild der Vena cava (gewöhnlich 30 cm Kathetermaß bei 15 Hrsg) angefertigt werden.
20. Entfernen Sie den Einführungsschleier und wenden Sie die Zugangsstelle entsprechend der Routine mit Kompression, um Hämostase zu erreichen.

Technik mit Führungsdraht

Die anatomische Unterschiede, die mit der Position des *Recovery* Filters auftreten können, kann eine Technik mit Führungsdraht gewählt sein.

Verwendung eines Führungsdrahts

Ist es schwierig, den Cone über die Spitze des *Recovery* Filters vorzuschieben, kann zugunsten präziseren Vorschubens der Cone über den Führungsdraht vorgeschoben werden.

Ziehen Sie Einführungsschleier und Conekatheter vor der Spitze des Filters zurück. Führen Sie einen 0,035" Führungsdraht (mit J-Spitze oder angewinkelter Spitze, es wird empfohlen, einen Führungsdraht mit hydrophiler Beschichtung zu verwenden) durch das Zentrallumen ein. Schieben Sie den Führungsdraht durch Cone und den Filter bis vor die Filterspitze.

Stellt fest, dass der Führungsdraht die Filterspitze berührt oder noch vor den Filterspitze liegt, schieben Sie den Cone über den Führungsdraht bis zur Filterspitze.

Schieben Sie das Einführungsschleier vor, bis der Cone sich leicht über den Filterspitze befindet. Ziehen Sie den Führungsdraht in den Schieberschaft zurück.

Fahren Sie mit der Bergung des Filters fort wie in Schritt 18 beschrieben.

J. Lieferumfang

Jeder *Recovery* Filter wird sterile geliefert in einer Aufbewahrungsbox geliefert. Bei ungeöffnete und unbeschädigter Packung ist jeder *Recovery* Filter steril und pyrogenfrei und für den Einmalgebrauch vorgesehen. Das Antikoagulationsmittel und das Schiebebesteckungssystem sind fertig montiert. Wenn der Filter versehentlich aus dem Rahmen gedrückt wurde, darf er nicht wieder eingesetzt werden.

Hinweis: Der *Recovery* Filter und seine Zubehörteile sowie die Materialien für die Einführung sind nach Gebrauch potenziell biogefährlich. Behandeln und entsorgen Sie die Produkte entsprechend anerkannter medizinischer Praxis und aller anwendbaren Gesetze und Vorschriften.

Bewahren Sie den *Recovery* Filter kühl (Raumtemperatur) und trocken auf.

K. Garantie

Bard garantiert dem Erstverbraucher dieses Produktes für ein Jahr ab dem Datum des Kaufes, dass dieses Produkt frei von Material- und Verarbeitungsfehlern ist. In Rahmen dieser eingeschränkten Garantie erfolgt die Gewährleistung nach alleinigem Ermessen von Bard durch Reparatur oder Austausch des defekten Produktes oder durch Erstattung des gezahlten Nettokaufpreises. Durch normale Benutzung verursachte Verschleiß und durch Missbrauch des Produktes entstandene Defekte fallen nicht unter diese eingeschränkte Garantie.

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Ausgabedatum: 1203

Sollten zwischen diesem Datum und der Verwendung des Produktes drei Jahre vergangen sein, so setzen sich der Anwender mit C. R. Bard, Inc. in Verbindung, um festzustellen, ob möglicherweise zusätzliche Produktinformationen vorliegen.

Bard, Recovery, und *Recovery Cone* sind eingetragene Warenzeichen von C. R. Bard, Inc. oder einer Tochtergesellschaft.

US-Patent: 6,007,558 und 6,258,026. Weitere Patente angemeldet.

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1. ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2000 (Res 12, geltig ab 01/01/01

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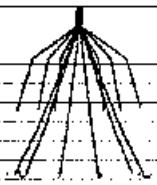
Sistema del Filtro Recovery®, da utilizzare nella vena cava



ITALIANO

Informazioni per l'uso

Attenzione: La legge federale degli Stati Uniti limita la vendita di questo prodotto esclusivamente da parte di un medico o dietro suo ordine.

A. Informazioni generali

Il Filtro *Recovery* oggi esiste la nuova generazione di dispositivi di intercettazione venosa concepiti per prevenire l'embolia polmonare. Il design e i materiali esclusivi del Filtro *Recovery* assicurano un'ottima efficienza filtrante e permettono la collocazione precisa e sicura per un introduttore progressivo standard del diametro interno di 7 French con estrema difficoltà. La procedura di collocazione è rapida ed eseguibile con facilità.

Il set comprende il progetto a modo da poter controllare all'interno del piccolo catetere di introduzione di 48 cm di lunghezza e diametro interno di 7 French, grazie a un filo spingitore flessibile e rotondo. Un cuscinetto all'estremità terminale del filo permette di spingere il vertice del filo, mentre un segmento scanalato consente di trattenere e orientare in modo appropriato le gambe del filo. Questi componenti assicurano il filo al filo spingitore durante l'avanzamento, con a punta in avanti, in direzione dell'estremità distale del catetere, particolare sulla vena renale inferiore. Quando la punta del filo raggiunge la punta del catetere di introduzione risultano ottimali i marker radiopachi presenti sul catetere di introduzione e il sistema di applicazione vengono quindi ritratti sopra l'impugnatura del filo spingitore, in modo da liberare e rilasciare il filo, permettendogli di assumere la forma predeterminata. Il sistema di centratura permette di impiantare il Filtro *Recovery* con la punta centrale e prevenire l'incrocio delle gambe.

Il Filtro *Recovery* è concepito come filtro permanente. Se indicato dal punto di vista clinico, il Filtro *Recovery* può essere rimosso per via percutanea dopo l'impianto, secondo le istruzioni riportate nella sezione "Procedura di rimozione facoltativa". I gambi elastici del Filtro *Recovery* contengono un filtro rigido e resistente alla migrazione, ma se deformano elasticamente durante la rimozione percutanea. (Per le istruzioni relative alla rimozione vedere la sezione Procedura di rimozione facoltativa.)

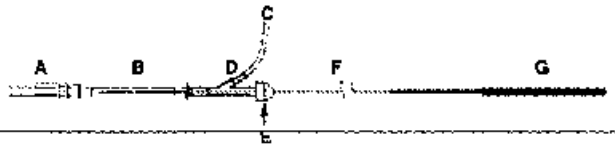
Compatibile con la procedura di *MRI*. L'impianto del Filtro *Recovery* è sicuro per la procedura di *MRI* e non si attende che il suo effetto sul funzionamento degli strumenti di *MRI*.

B. Descrizione del dispositivo

Il sistema del Filtro *Recovery* è costituito dal Filtro e dal Sistema di applicazione. Il Filtro *Recovery* è composto da dodici fili di nitinol con memorizzazione della forma, che si ripiegano da un mozzetto centrale di nitinol. Quattro dei fili di ritenzione degli emboli, le gambe direzionano il livello di filtrazione inferiore, mentre le piccole rappresentano i livelli di filtrazione superiori. Il Filtro *Recovery* è indicato per l'uso nella vena cava con diametri di fino a 28 mm.

Il Sistema di applicazione del Filtro *Recovery* è illustrato in Figura A. Il Sistema di applicazione è composto da: un introduttore a guaina del diametro interno di 7 French e con dilatatore, dal filtro *Recovery*, da un tubo di conservazione ospita il filtro per l'erogazione di soluzione salina e da un sistema di spinta. Il Filtro *Recovery* è confezionato premontato all'interno del tubo di conservazione per l'applicazione.

Figura A. Sistema del Filtro Recovery



A CATETERE DI INTRODUZIONE
B TUBO DI CONSERVAZIONE DEL FILTRO
C SET PER L'INFUSIONE (BOCCA A BOCCA) DI SOLUZIONE SALINA
D PORT LATERALE
E ADATTATORE REGOLABILE TOUHY-BORST
F FILO SPINGITORE RIMOVIBILE
G INSERITORE DEL FILO SPINGITORE

IMPORTANTE: Leggere attentamente le istruzioni prima di utilizzare il Filtro Recovery.

C. Indicazioni per l'uso

Il Sistema del Filtro *Recovery* è indicato per la prevenzione dell'embolia polmonare ricorrente mediante intercettazione nella vena cava delle seguenti situazioni:

- Tromboembolia polmonare quando è controindicata l'uso di anticoagulanti
- Insuccesso della terapia anticoagulante in caso di patologia tromboembolica
- Trattamento di complicanze in seguito a embolia polmonare massiva in cui i benefici previsti della terapia convenzionale sono ridotti
- Embolia polmonare cronica ricorrente quando la terapia anticoagulante non ha avuto successo oppure è controindicata

Il Filtro Recovery può essere rimosso seguendo le istruzioni riportate nella sezione "Procedura di rimozione facoltativa" del Filtro

D. Controindicazioni

ATTENZIONE: Se il diametro corretto della vena cava inferiore (VCI) supera i 28 mm il filtro non deve essere inserito all'interno della VCI.

Il Filtro Recovery non deve essere impiantato in:

- Pazienti in stato di gravidanza se la fluoroscopia può mettere in pericolo il feto. Valutare attentamente i rischi e i benefici
- Pazienti con un diametro della vena cava superiore a 28 mm
- Pazienti a rischio di embolia settica

E. Avvertenze

Impianto del Filtro Recovery

1. Il Filtro *Recovery* per la vena cava è progettato all'interno di un kit di posizionamento ed è concepito esclusivamente come prodotto monouso. Non applicare il filtro prima di averlo controllato attentamente all'interno della vena cava (VCI), in quanto il Filtro *Recovery* non può essere rimosso in modo sicuro nel kit di conservazione.
2. L'applicazione del Filtro *Recovery* attraverso il catetere di introduzione può rivelare eccessiva resistenza durante l'estrazione del filo spingitore durante l'applicazione provocando causare il distacco del filtro. Il ritiro della guaina o della guaina dello stesso e potrebbe prevenire l'ulteriore avanzamento all'interno della guaina
3. Il Sistema del Filtro *Recovery* è concepito unicamente per accesso femorale. Non utilizzare mai il Filtro *Recovery* e il Sistema di applicazione nel corso di approcci superiori vena giugulare, succlavia o antecubitale) poiché ciò aumenta un allontanamento improprio del Filtro *Recovery* all'interno della vena cava inferiore.
4. Se il sito di applicazione indicato è a presenza un trombo ingente, non cercare di applicare il filtro attraverso tale trombo. L'applicazione del filtro attraverso un tale elemento. Un trombo a dimensioni limitate può essere attraversato dal filo guida e dall'introduttore
5. Per la rimozione del Filtro *Recovery* utilizzare unicamente il Sistema di Rimozione *Recovery Cone*. Non rimuovere con un altro prodotto
6. Non avanzare mai il filo guida e l'introduttore/dilatatore oppure ritirare il filo senza l'ausilio di guida fluoroscopica

Rimozione del Filtro Recovery

1. Non cercare di rimuovere il Filtro *Recovery* se all'interno del filtro sono presenti quantità significative di trombo oppure se la punta del filtro è incastrata nella parete della vena cava.
2. Per la rimozione del Filtro *Recovery* utilizzare unicamente il Sistema di Rimozione *Recovery Cone* della Bard venduto separatamente. L'uso di altri dispositivi potrebbe provocare lesioni

F. Precauzioni

Impianto del Filtro Recovery

1. In donne in stato di gravidanza in cui sia fatale il filtro deve essere collocato preferibilmente sotto il livello renale
2. Varicelle anatomiche possono rendere più difficile l'inserimento e l'applicazione del Sistema *Recovery Cone*. Seguendo attentamente queste istruzioni per l'uso si possono abbreviare i tempi di inserimento e prevenire eventuali difficoltà
3. Deformazioni spinali: Particolare cautela va posta quando si intende impiantare il Filtro *Recovery* in pazienti con deformazioni spinali (cifoscoliosi) significative, in quanto la vena cava inferiore può seguire il corso di queste deformazioni anatomiche, le quali rendono più difficile il tentativo avanzato per recuperare il filtro.

G. Possibili complicanze

Migrazione del filtro. Potrebbe essere causata dalla collocazione di una vena cava con diametro superiore a 28 mm o se non sono state adottate tecniche di ancoraggio appropriate

Perforazione della parete della vena cava. Può verificarsi se non sono state adottate tecniche di avanzamento appropriate

Contatto caudale. La probabilità di questo evento deve essere valutata rispetto al rapporto rischio/beneficio relativo a un paziente con embolia polmonare in corso o pericolo e in mancanza di intervento

H. Articoli necessari

Per l'uso sono necessari i seguenti articoli:

- Un Filtro *Recovery* e un Sistema di applicazione che contiene:
  - Un set con catetere di applicazione lungo 48 cm e con diametro interno di 7 French e con dilatatore.
  - Un tubo di conservazione contenente il Filtro *Recovery* e il sistema di applicazione a spinta premontati.
  - Un filo guida da 0.035 pollici per punte a J da 3 mm di lunghezza pari a 110 cm o superiore
  - Ago di entrata da 18 Gauge
  - Soluzione salina
  - Tubo sterile di estensione per l'infusione e la somministrazione generale a pompa di soluzione salina
  - Tutto il necessario per la venipuntura locale, lame n. 11, mezzo di contrasto, teli sterili, ecc.
  - Un kit di entrata costituito da un filo guida da 0.035 pollici con punta a J da 3 mm, ago di entrata, bisturi n. 11 e ago da 18 Gauge per la venipuntura locale, lame n. 11, mezzo di contrasto, teli sterili, ecc.

Se il medico opta per la rimozione percutanea del Filtro *Recovery*, il Sistema di Rimozione *Recovery Cone* è disponibile da:

G.-H. Sterilizzo

I. Istruzioni per l'uso

Inserimento del Catetere di introduzione da 7 French e venografia preliminare

1. Selezionare una via di accesso idonea nella vena femorale sul lato destro o sinistro, a seconda della conformazione anatomica del paziente, della preferenza del operatore e dalla presenza della trombosi venosa.
2. Preparare, coprire con teli sterili e anestetizzare il sito di puntura secondo le procedure standard.
3. Selezionare e aprire la confezione del filtro. Aprire la confezione del Kit A contenente il Catetere di introduzione.
4. Inserire la cute con una lama n. 11 ed effettuare la venipuntura con un ago di entrata da 18 Gauge.
5. Inserire il filo guida con punta a J e farlo avanzare delicatamente all'interno della vena cava distale e della vena iliaca.

NB: Se si incontra della resistenza durante la procedura di inserimento forzato, ritirare il filo guida e controllare mediante fluoroscopia la presenza della vena iliaca/vena cava inferiore una piccola quantità di mezzo di contrasto. Se è presente un trombo ingente, estrarre l'ago per la venipuntura e tentare l'inserimento nella vena sul lato opposto. Un trombo di dimensioni ridotte può essere oltrepassato dal filo guida e dall'introduttore.

6. Estrarre l'ago per la venipuntura sopra il filo guida con punta a J. Far avanzare, all'interno della vena cava distale e della vena iliaca comune, il filo guida, il catetere di introduzione da 7 French assieme al dilatatore all'interno.

NB: Il catetere di introduzione presenta marker radiopachi che facilitano la visualizzazione e il posizionamento del filtro prima dell'applicazione. I marker radiopachi sul catetere di introduzione forniscono una posizione "bersaglio" entro cui collocare il filtro immediatamente prima dell'estrazione della guaina e dell'applicazione.

7. Rimuovere il filo guida e il dilatatore, mantenendo il catetere di introduzione con la punta nella vena cava distale o nella vena iliaca. Per mantenere la pervietà del catetere, eseguendo manualmente e intermittenza e collegare il catetere un sistema per l'infusione continua goccia a goccia di soluzione salina.

NB: Il raccordo del sistema di introduzione è progettato con un design interno speciale. Prestare attenzione e effettuare le connessioni con fermezza, ma evitando una forza eccessiva che potrebbe causare la rottura del raccordo.

8. Effettuare una venografia caudale della vena cava inferiore (idealmente 30 ml di mezzo di contrasto a 15 ml/s). Controllare la presenza di trombi caudali e di anomalie congenite, nonché la posizione delle vene renali. Selezionare il livello ottimale per la collocazione del filtro a minore o il diametro della CVI, ingrandendo il più possibile (fino a 28 mm).

6. Far avanzare l'estremità di introduzione al livello selezionato servendosi di guida fluoroscopica. Per facilitare questa operazione l'filo guida e l'dilatatore devono essere rimossi. Per l'inserimento femorale la punta del catetere di introduzione deve trovarsi 1 cm sotto la vena renale inferiore.
10. Estrarre il filo e il sistema di applicazione dalla B.
11. Collegare una siringa da 50 ml di soluzione salina sterile eparinizzata all'emostatica a Y fornita con set di rimozione Recovery. Lavare fluendo la soluzione salina attraverso il filo nell'ago di conservazione per 5 secondi, in modo da assorbirlo prima del passaggio attraverso il catetere di introduzione. Regolare il set di rilascio in modo da ottenere una velocità di gocciolamento elevata. Si impedisce la velocità della soluzione fredda-flusso non sufficiente a ridurre la temperatura corporea centrale e impedisce il filo di impedire il movimento libero durante.

NB: È molto importante mantenere la pervietà del catetere di introduzione mediante il flusso di soluzione salina. In modo che il segmento sporgente che consente opportunamente le gambe del filtro non si ostruisca. Ciò potrebbe inibire o addirittura inibire l'applicazione del filtro.

12. Collegare l'estremità libera del tubo di conservazione del filtro direttamente al catetere di introduzione per rilasciare il filtro per mezzo della guida senza attraversare la VCI. Per minimizzare l'aria intrappolata tra il catetere di introduzione e il sistema di applicazione del filtro

Avanzamento del Filtro, Illustrato

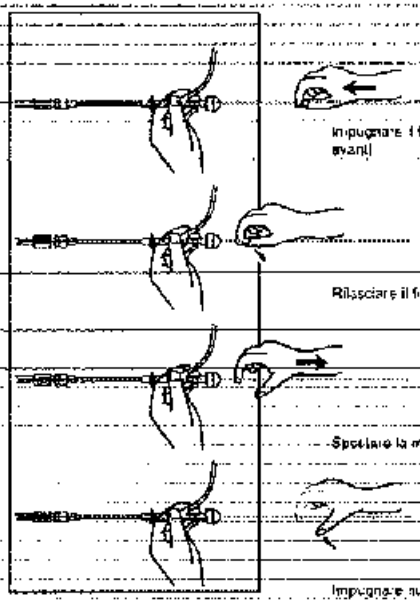


FIGURA B
FIGURA C
FIGURA D
FIGURA E

13. Far avanzare il filtro muovendo in avanti il filo spingitore in nitinol attraverso il catetere di introduzione tenendo saldamente il filtro con ogni movimento in avanti del filo spingitore (Figura B-E). Non ritrarre il filo spingitore, farlo solamente avanzare. Far scorrere l'operatore il filo spingitore in nitinol può essere ruotato, senza provocare pericoli, del nitinol, per facilitare la manipolazione e l'avanzamento del filo spingitore.
14. Continuare il movimento in avanti del filo spingitore fino a che la punta del filtro raggiunge l'anello radiopaco all'estremità distale del catetere di introduzione. A questo punto l'impugnatura del filo spingitore dovrebbe trovarsi in prossimità dell'apertura a Y.

Rilascio/applicazione del filtro

15. Applicare e rilasciare il filtro seguendo la sequenza seguente:

Figura F: Tenere saldamente l'impugnatura del filo spingitore

Figura F-1: Filtro posizionato all'interno del catetere di introduzione per mettere radiopaca prima dell'applicazione nella VCI

NB: Non applicare il filtro spingendo il filo nell'estremità del catetere di introduzione. Rimuovere invece la guida dal filtro stazionario mentre il catetere di introduzione come descritto in seguito.

Rilascio del filtro, Illustrato

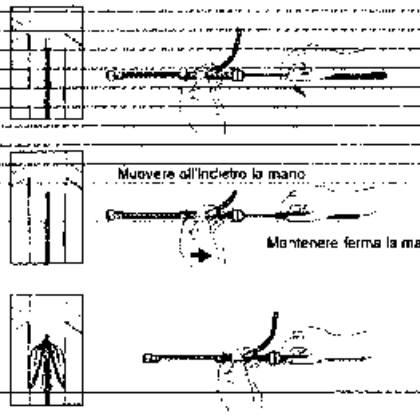


FIGURA F
FIGURA F-1
FIGURA G
FIGURA G-1
FIGURA H
FIGURA H-1

Per rilasciare il filtro semplicemente la guida all'interno della VCI come segue:

Posizionare la punta del Filtro 1 cm sotto la vena renale inferiore.

Figura G: Mantenendo ferma una mano, utilizzare l'altra mano per ritrarre l'adattatore a Y e il tubo di conservazione completamente aperta l'impugnatura, scoprendo e rilasciando il filtro.

Figura G-1: Estrazione del Filtro dalla guida nella VCI

Figura H-1: La posizione della mano al termine della procedura di estrazione della guida

Figura H-1: Filtro a permanenza nella VCI

16. Ritirare il filo spingitore nel tubo di conservazione estraendo fermamente l'adattatore a Y, il tubo di conservazione e il gruppo del catetere di applicazione e l'inguine all'interno il filo spingitore.
17. Per mantenere la pervietà del catetere, irrigarlo a intervalli regolari con una siringa piena di soluzione salina eparinizzata.

Venografia di controllo della vena cava

18. Si può eseguire una venografia di controllo della vena cava attraverso il catetere di introduzione per confermare il corretto posizionamento del filtro (solitamente 30 ml di mezzo di contrasto a 15 ml/s)
19. Rimuovere il catetere di introduzione e comprimere il sito di puntura secondo la procedura consueta per arrestare il sanguinamento.

PROCEDURA DI RIMOZIONE FACOLTATIVA DEL FILTRO:

Rimozione del Filtro Recovery

ATTENZIONE: Si consiglia caldamente di effettuare la rimozione del Filtro Recovery entro 55 giorni dall'impianto.

Articoli necessari

Per l'uso sono necessari i seguenti articoli:

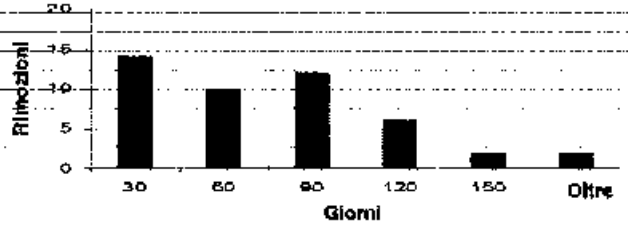
- 1 Sistema di Rimozione Recovery Conedle contenente:
  - Un set con catetere di applicazione lungo 75 cm e con diametro interno di 10 French e con dilatatore
  - Un adattatore a Y con Recovery Cone e sistema di applicazione a spinta
- Un filo guida da 0,035 pollici con punta a J da 3 mm di lunghezza per la 110 cm e superiore
- Ago di entrata da 18 Gauge
- Dilatatore da 12 French
- Soluzione salina
- Tubo sterile di estensione per l'infusione di soluzione salina guidata o siringa per l'infusione di soluzione salina
- Tutto il necessario per la venipuntura (bisturi, lame n. 11, anestetico locale, telo sterile, ecc.

Esperienza clinica

I Filtri Recovery sono stati usati in Canada da un unico sperimentatore e due colleghi in sei ospedali collaudati di Toronto su 55 soggetti in controlli retrospettivi "Special Access".

Nonostante i dispositivi possano essere rimossi mediante un approccio femorale, la rimozione è stata effettuata da tre medici esperti di accesso endovascolare e imaging clinico.

Dei 52 filtri impiantati, 44 sono stati rimossi. I tentativi di rimozione sono riusciti con i filtri impiantati per un periodo compreso tra 14 e 1.161 giorni, con una media di 60 giorni (vedi istogramma).



Il follow-up dopo la rimozione è durato in media 385 giorni (intervallo compreso tra 1.991 giorni). La maggior parte dei filtri è stata rimossa attraverso la vena giugulare interna destra, ma alcuni sono stati rimossi attraverso la vena giugulare interna sinistra (n=1) e la vena giugulare collaterale (n=1). Un filtro è stato impiantato chirurgicamente durante un'operazione di resezione di un tumore e questo la massa tumorale aderiva molto al suo interno. Sono stati descritti anche altri metodi per l'avanzamento del filtro per recuperare il filtro in tutti i casi eccetto 4, in cui è stato utilizzato un introduttore più largo, oppure è stato lacerato il tubo di un tessuto con una pinza al posto del Sistema Recovery Cone. Quando è stato utilizzato un introduttore più largo non si è verificato nessun caso di embolia polmonare asintomatica.

L'unico evento avverso riportato è stato la rottura del braccio e del gambo del filtro. Questo filtro era stato impiantato in una persona di 62 anni con il braccio destro interno e il gambo del filtro. Durante il tentativo di rimozione, il gambo del filtro si è rotto in posizione inferiore, che ha provocato una deviazione significativa del gambo e la sua penetrazione nella parete addominale. Il filtro è stato recuperato, ma privo del gambo.

Tabella di riepilogo dell'esperienza clinica	
Filtri Recovery impiantati	52
Rimozioni percutanee dei filtri	45
Rimozione chirurgiche dei filtri	1 (Concomitante a resezione tumorale)
Età dei pazienti	8-89 anni (media 52 anni)
Motivo dell'impianto del Filtro	
Controindicazioni alla terapia anticoagulante	46
Complicanze associate alla terapia anticoagulante	13
Terapia anticoagulante non riuscita	3
Profilassi	2
Tempo alla rimozione	1-161 giorni (media 60 giorni)
Follow-up dopo la rimozione	1-991 giorni (media 385)
Complicanze associate alla rimozione del Filtro	
Trombosi	0
Rottura del gambo in seguito alla trazione provocata dal braccio e dal gambo del dispositivo rilasciato	1
Embolia polmonare asintomatica dopo la rimozione	1

Istruzioni procedurali

Inserimento del Catetere di Introduzione

1. Selezionare una via di accesso idonea, ad es. vena giugulare sul lato destro o sinistro o vena(e) della coscia(e) e avvolgere del paziente, data la preferenza dell'operatore e della posizione della lesione venosa.
2. Preparare, coprire con teli sterili e anestetizzare il sito di puntura secondo la procedura standard.
3. Selezionare e aprire il contenitore del catetere *Recovery Cone*. Aprire la confezione del filo *Accompagnato* il Catetere di introduzione.
4. Inserire l'ago 21G (0,7 mm) fornito nel kit attraverso la venipuntura sul lato destro del corpo.
5. Inserire il filo guida e farlo avanzare delicatamente fino alla posizione del filtro *Recovery* da rimuovere.
6. Estrarre l'ago per la venipuntura e sopra il filo guida.
7. Per dilatare il vaso inserire con un dilatatore da 12 French.
8. Fare avanzare all'interno della vena e sopra il filo guida, il catetere di introduzione. Il dilatatore può essere estratto a questo punto.

NB: Il catetere di introduzione potrebbe un marker radiopaco all'estremità distale del catetere, che ne migliora la visibilità.

9. Rimuovere il filo guida e il dilatatore, mantenendo il catetere di introduzione con la punta nella posizione appropriata. Per mantenere la pervietà del catetere, sciacquarlo periodicamente e intermittente o collegare al catetere un sistema per infusione continua guidata a goccia di soluzione salina.
10. Ottenere una venografia standard della vena cava inferiore (solitamente 30 ml di mezzo di contrasto a 15 ml/s). Verificare la presenza di trombo all'interno del filtro. Se all'interno del filtro è presente una quantità notevole di trombo, rimuovere il Filtro *Recovery*.

Inserimento e applicazione del Recovery Cone

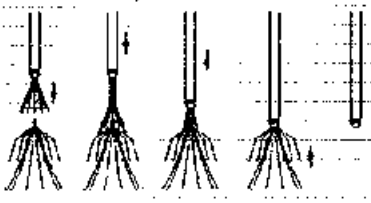
11. Estrarre il cono e il catetere di aspirazione a spirale dal Kit.
12. Bloccare il fermo centrale del catetere del cono e bagnare il cono con soluzione salina - preferibilmente eparinizzata.
13. Ritrarre lentamente il cono all'interno del dilatatore a Y per far avanzare il cono.

NB: Prima di collegare il sistema al catetere di introduzione, il cono deve essere ritratto completamente all'interno del dilatatore a Y, per poter essere applicato facilmente attraverso il catetere.

14. Collegare una siringa da 60 ml e una lunga di soluzione salina al port laterale del dilatatore a Y, lasciare fuori la valvola stantia al cono di rimozione nell'adattatore a Y per 5 secondi. Spingere la valvola dell'adattatore Touhy-Borst per minimizzare il rilascio di soluzione salina verso l'esterno, ma non dimenticare troppo, poiché è impossibile che il catetere spingitore di muoversi liberamente.
15. Collegare l'estremità maschio del dilatatore a Y contenente il cono richiuso direttamente al catetere di introduzione. Per minimizzare il rischio di aspirazione dell'aria nel catetere di introduzione, è fondamentale applicare il dilatatore a Y.
16. Far avanzare il cono muovendo il catetere spingitore in avanti attraverso il catetere di introduzione, assicurarsi il cono con ogni movimento in avanti del catetere spingitore.
17. Continuare il movimento in avanti del filo spingerlo fino a che il cono raggiunge il marker radiopaco all'estremità distale del catetere di introduzione. Per far avanzare il cono ritrarre il catetere mantenendo fermo il catetere spingitore.

Cattura del Filtro *Recovery*

Rimozione del Filtro, Illustrata



18. Le catture del Filtro *Recovery* è illustrato nelle Figure B-F.

Figura B: Dopo che il cono è stato spostato posizione superiore del Filtro, far avanzare il cono sulla punta del Filtro mantenendo fermo il catetere di introduzione e facendo avanzare il catetere spingitore. Si consiglia di ottenere prima un'immagine fluoroscopica anteriore-obliqua per confermare la posizione corretta del cono sopra la punta del Filtro.

Figura C: Richiudere il cono sopra la punta del Filtro facendo avanzare il catetere di introduzione sopra il cono mentre si mantiene fermo il catetere spingitore.

Figura D: Continuare a far avanzare il catetere di introduzione sopra il cono fino a quando il cono si trova all'interno del catetere di introduzione.

Figura E: Con il cono richiuso sopra il Filtro, rimuovere il Filtro mantenendo fermo il catetere di introduzione e ritirando il catetere spingitore con un movimento costante e uniforme.

Figura F: Il Filtro è stato ritirato all'interno del catetere.

Venografia di controllo della vena cava

19. Si può effettuare una venografia di controllo della vena cava dopo la rimozione del catetere di introduzione (solitamente 30 ml di mezzo di contrasto a 15 ml/s).
20. Rimuovere il catetere di introduzione e comprimere il sito di puntura secondo la procedura consueta per pervenire ad emostasi.

Filo guida – Tecnica assistita

A causa della variabilità anatomica rispetto alla posizione del Filtro *Recovery* si possono riscontrare difficoltà nell'uso del filo guida.

Uso del filo guida

Se risulta difficile far avanzare il cono sopra la punta del Filtro *Recovery*, è possibile utilizzare un filo guida per facilitare l'avanzamento del cono sulla punta del filtro.

Rimuovere l'introduttore e il catetere del cono dalla posizione della punta del Filtro. Inserire un filo guida da 0,035 pollici attraverso il lume centrale (con punta a J o angolata, si consiglia un filo guida idrofilico). Far avanzare il filo guida attraverso il cono e il Filtro fino ad avvicinarsi alla punta del Filtro.

Dopo aver confermato che il filo guida è in contatto con la punta del Filtro o in sua prossimità, far avanzare il cono sopra il filo guida fino alla punta del Filtro.

Avanzare l'introduttore per far richiudere parzialmente il cono sulla punta del Filtro. Retrarre il filo guida attraverso il catetere spingitore.

Continuare a rimuovere il Filtro come descritto al punto 18.

J. Formato di vendita

Ogni Filtro *Recovery* è sterile e non pirogeno, alla confezione chiusa e integra, ed è pronto per l'applicazione come prodotto esclusivamente monouso. Il sistema di rimozione *Recovery Cone* è fornito parimenti sterile. Se il filtro viene rilasciato inavvertitamente, non cercare di recuperarlo o riposizionarlo.

K. Garanzia

Bard garantisce al acquirente originale che il prodotto sarà esente da difetti di materiali e manodopera per un periodo di un anno dalla data originale di acquisto. Ai sensi di questa garanzia limitata la nostra responsabilità riguarderà unicamente la riparazione o sostituzione del prodotto difettoso, ad esclusiva discrezione di Bard, oppure il rimborso del prezzo pagato dall'acquirente. La presente garanzia limitata non include il normale consumo o logoramento del prodotto dovuto, per esempio, dall'ordinario uso del presente prodotto.

SALVO QUANTO PREVISTO DALLE LEGISLAZIONI IMPERATIVE, QUESTA GARANZIA LIMITATA SOSTITUISCE TUTTE LE ALTRE GARANZIE, ESPLICITE O ESPLICITE, COMPRESE FRA L'ALTRO, LE GARANZIE IMPLICITE DI COMMERCIABILITÀ O IDONEITÀ DEL PRODOTTO PER UNA FINALITÀ SPECIFICA. LA RESPONSABILITÀ DI BARD NON SARÀ MAI SUPERIORE AL COSTO DI ACQUISTO DEL PRODOTTO DIFETTOSO. BARD NON SARÀ RESPONSABILE PER EVENTUALI DANNI INCIDENTALI O INDIRETTI DERIVANTI DA O CAUSATI DALL'USO DI QUESTO PRODOTTO, SIA CHE TALI DANNI SIANO PREVEDIBILI O MENO E ANCHE SE BARD È STATA AVVISATA DELLA POSSIBILITÀ DI TALI DANNI. NESSUNA PERSONA HA L'AUTORITÀ DI ASSUMERE PER CONTO DI BARD ALTRE RESPONSABILITÀ O GARANZIE RELATIVE A QUESTO PRODOTTO, SALVO QUANTO ESPRESSAMENTE DICHIARATO NELLA PRESENTE GARANZIA LIMITATA. BARD NON AUTORIZZA NESSUNA PERSONA A CREARE PER SUO CONTO ALTRE OBBLIGAZIONI O RESPONSABILITÀ RELATIVE A QUESTO PRODOTTO. QUESTA GARANZIA LIMITATA È SOGGETTA A QUANTO PREVISTO DALLE LEGISLAZIONI IMPERATIVE E DEI DIRITTI STATUTARI DEL CONSUMATORE.

Data della redazione: 12/03

Nel caso in cui siano passati 3 anni da tale data al uso del prodotto, si prega l'utente di rivolgersi alla C.R. Bard, Inc. per assicurare la disponibilità di ulteriori informazioni relative al prodotto.

Bard, Recovery e Recovery Cone sono marchi registrati di C. R. Bard, Inc. o di una sua affiliata.

Brevetti americani N. 6,090,666 e 6,258,026. Altri brevetti in stesso o regolarizzato

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Riferimenti bibliografici:

1. ACR Standard for The Performance Of Percutaneous Pharmacal Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2008 (Res 32, Effective 01.01.11)

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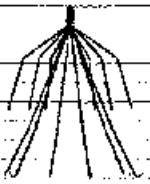
Sistema de Filtro Recovery®
para el uso en la vena cava



ESPAÑOL

Instrucciones de empleo

Advertencia: Las leyes federales de EE.UU. limitan la venta de este dispositivo a los médicos o bajo prescripción facultativa.

A. Información general

El Filtro *Recovery* representa una nueva generación de dispositivos de intercepción retirables diseñados para evitar las embolias pulmonares. El diseño singular y el material del Filtro *Recovery* proporcionan una eficacia de filtración excelente y permiten la colocación percutánea a través de una vaina introductora angiográfica convencional de 8,5 Fr/French con un mínimo de dificultades en el lugar de introducción. El procedimiento de colocación es rápido y fácil de realizar.

El equipo femoral está diseñado para avanzar a lo largo de su catéter introductor de 45 cm, 6 Fr/French utilizando una guía impulsora de núcleo flexible. Una punta roma en el extremo de la guía está diseñada para impulsar el ápice del filtro y un segmento con ranura está diseñado para sujetar y orientar de forma apropiada las patas del filtro. Estos componentes fijan el filtro en la guía impulsora a medida que avanza el filtro, con la punta hacia delante, hasta el extremo distal del catéter, ubicado en el destino de la vena cava inferior. Cuando la punta del filtro se aproxima a la punta del catéter introductor, se encontrará entre un mandril y conectores en el catéter introductor. A continuación, el catéter introductor y el sistema de liberación se retiran hasta el tronco de la pata impulsora para dejar expuesto y liberar el filtro y dejar que recobre su configuración predeterminada. El sistema para centrar permite que el Filtro *Recovery* se libere con la punta del filtro centrada y ambas patas se crucen.

El Filtro *Recovery* está diseñado para actuar como un filtro permanente. Cuando esté clínicamente indicado, el Filtro *Recovery* podrá retirarse de forma percutánea después de la implantación según las instrucciones facilitadas en la sección Procedimiento de extracción opcional. Los pacientes a quienes el Filtro *Recovery* permiten que el filtro se mantenga rígido y se resista al desplazamiento, pero también permiten que se deforme elásticamente cuando se vaya a retirar percutáneamente. (Vease Procedimiento de extracción opcional para circunstancias especiales de extracción).

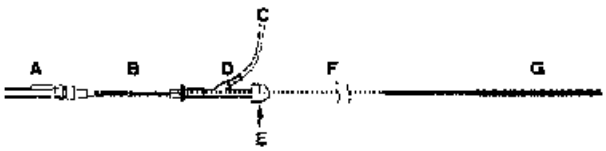
Compatible con IRM. Las pruebas de Filtro *Recovery* no sugieren que IRM y los artefactos no se vean afectados por el funcionamiento de un aparato de IRM.

B. Descripción del dispositivo

El Sistema de Filtro *Recovery* consta del filtro y del sistema de liberación. El Filtro *Recovery* consta de doce guías de metal con memoria de forma, que están de una sola pieza de níquel titanio. Estas doce guías forman dos niveles de filtración de 6 hebras. Las puntas proporcionan el nivel inferior de filtración y los brazos proporcionan el nivel superior de filtración. El Filtro *Recovery* está destinado al uso en la vena cava con diámetros de hasta 28 mm.

En la Figura A aparece ilustrado el Sistema de liberación del Filtro *Recovery*. El sistema de liberación consta de una vaina introductora con un diámetro interior de 7 Fr, un dilatador, el Filtro *Recovery*, un tubo de almacenamiento con su punto de infusión de solución salina y un sistema impulsor. El Filtro *Recovery* se encuentra precargado dentro del tubo de almacenamiento de liberación.

Figura A. Sistema de Filtro Recovery



A. CATÉTER INTRODUCTOR
B. TUBO DE ALMACENAMIENTO DEL FILTRO
C. EQUIPO DE INFUSIÓN DE PUNTO DE SOLUCIÓN SALINA
D. ORIFICIO LATERAL
E. ADAPTADOR TOUHY-BORST AJUSTABLE
F. GUÍA IMPULSORA DE NÚCLEO
G. MANGO DE LA GUÍA IMPULSORA

IMPORTANTE: Lea detenidamente las instrucciones antes de usar el Filtro *Recovery*.

C. Indicaciones para el uso

El Sistema de Filtro *Recovery* está indicado para el uso en la prevención de la embolia pulmonar recurrente mediante su colocación permanente en la vena cava en las siguientes situaciones:

- Tromboembolia pulmonar cuando los anticoagulantes estén contraindicados
- Fracaso de la terapia anticoagulante para la enfermedad tromboembólica
- Traumatismo de urgencia tras una embolia pulmonar cuando se sospecha que los beneficios de la terapia con anticoagulantes son pequeños.
- Embolia pulmonar crónica recurrente cuando la terapia con anticoagulantes haya fracasado o este contraindicada.
- El Filtro *Recovery* podrá extraerse conforme a las instrucciones facilitadas en la sección Procedimiento opcional para la extracción del filtro.

D. Contraindicaciones de uso

ADVERTENCIA: Si el diámetro corregido de la vena cava inferior es mayor de 28 mm, no deberá introducirse el filtro en la vena cava inferior.

El Filtro Recovery no deberá implantarse en:

- Mujeres embarazadas cuando la fluoroscopia pueda suponer un peligro para el feto. Deberán valorarse cuidadosamente los beneficios y los riesgos.
- Pacientes cuyos diámetros de la vena cava sean inferiores de 28 mm.
- Pacientes con riesgo de embolia séptica.

E. Avisos

Implantación del Filtro Recovery

1. El Filtro *Recovery* para la vena cava está precargado en el tubo de almacenamiento estéril y está indicado para un solo uso. No lleve a cabo antes de su correcta colocación en la vena cava inferior, ya que el Filtro *Recovery* no puede volverse a recargar con seguridad dentro del tubo de almacenamiento.
2. La liberación del Filtro *Recovery* a través de la vaina introductora sólo podrá realizarse hacia delante. La retracción de la guía impulsora durante la liberación podría dar producir el desprendimiento del filtro, enganchando las patas o haciendo que el filtro no avance más dentro de la vena.
3. El Sistema de Filtro *Recovery* está indicado sólo para vías de acceso femorales. Nunca se deberá utilizar el Filtro *Recovery* y el sistema de liberación en vías de acceso alternativas (venas yugular, subclavia o antecubital) ya que esto daría lugar a la inserción incorrecta del Filtro *Recovery* dentro de la vena cava inferior.
4. Si hay un trombo grande en el lugar ideal de liberación, avance el filtro a través de él. Libere la vaina y el filtro a través de un lugar alternativo. Se podrá atravesar un trombo pequeño con la guía y el introductor.
5. Para extraer el Filtro *Recovery*, utilice únicamente el Sistema de extracción *Recovery Cone*. Nunca vuelva a colocar el filtro dentro.
6. Nunca haga avanzar la guía o la vaina introductora dentro o fuera del filtro sin visualización fluoroscópica.

Extracción del filtro Recovery

1. No intente extraer el filtro *Recovery* cuando haya cumplido los componentes de fijación completos dentro del filtro o esté pegado de la pared de la vena cava.
2. Para recuperar el Filtro *Recovery*, utilice únicamente el Sistema de extracción *Recovery Cone* de Bard (previsto aparte).
3. Fuera de las indicaciones no aprobadas anteriormente, no existen estudios que demuestren la seguridad y eficacia de la extracción del filtro *Recovery*.

F. Precauciones

Implantación del Filtro Recovery

1. En mujeres embarazadas y en mujeres en edad fértil, el filtro deberá colocarse en la posición suprarenal.
2. Las alteraciones anatómicas pueden complicar la inserción y la aplicación del filtro. La atención detenida a estas instrucciones de empleo puede disminuir el tiempo de inserción y reducir la probabilidad de que aparezcan dificultades.
3. Deformaciones en la columna: Es importante tener cuidado cuando se contemple la extracción del Filtro *Recovery* con el Sistema de extracción *Recovery Cone* en pacientes con deformaciones osteoarticulares importantes en la columna ya que la vena cava inferior puede seguir el curso general de dichas deformaciones anatómicas. Esto podría hacer necesario el uso de técnicas avanzadas para sacar el filtro.

G. Posibles complicaciones

- Desplazamiento del filtro. Se puede producir por la colocación en la vena cava inferior de diámetro superior a 28 mm o si no se utilizan las técnicas de anclaje apropiadas.
- Perforación de la pared de la vena cava. Se puede producir si no se utiliza la técnica de introducción aprendida.
- Oclusión de la vena cava. Deberá sopesarse la posibilidad de que exista ese riesgo inherente para un paciente que tenga estasis patológica o que se someta a una intervención.

H. Equipo necesario

Se necesita el siguiente equipo para el uso:

- Un Filtro *Recovery* y el Sistema de liberación *Recovery Cone* que contenga:
  - Una vaina introductora de 8,5 Fr, 45 cm, y un equipo dilatador
  - Un tubo de almacenamiento con el Filtro *Recovery* precargado y el sistema de liberación impulsor
  - Guía con punta en J de 0,035", 3 mm, de 110 cm de longitud o más
  - Aguja introductora de calibre 18
  - Solución salina
  - Tubo de extensión estéril para goteo e infusión de solución salina
  - Todos los materiales básicos para la venopunción: antiséptico, campitos de tela, anestésico local, gasas, etc.
  - Un kit de introducción que contenga una guía con punta en J de 0,038", 3 mm, aguja introductora, escalpelo del nº 11 y jeringa de 10 cc, dependiendo de la talla, número de catálogo 00406.

Si el médico elige la extracción percutánea del filtro *Recovery*, el Sistema de extracción *Recovery Cone* está disponible de C. R. Bard, Inc.

I. Instrucciones de empleo

Inserción del Catéter Introductor de 7 Fr. y venopunción preliminar

1. Seleccione una vía de acceso venoso femoral apropiada, bien sea en el lado derecho o izquierdo, dependiendo del tamaño y anatomía del paciente, de la preferencia del cirujano o de la ubicación de la bombona de oxígeno.
2. Prepare, cubra con paños quirúrgicos y anestesie el lugar de punción en la piel de la forma convencional.
3. Seleccione y abra el envase del catéter introductor del filtro *Recovery*.
4. Corte ligeramente la piel con una cuchilla del nº 11 y realice una venopunción con una aguja introductora del calibre 18.
5. Inserte la guía con punta en J a través de la aguja introductora en la vena cava distal y en la vena iliaca.

NOTA: Si se encuentra resistencia durante una introducción de la guía, retire la guía y compruebe la permeabilidad de la vena mediante fluoroscopia con una pequeña inyección de medio de contraste. Si hay un trombo grande, retire la aguja de venopunción e intente con la vena del lado contrario. Se podrá atravesar un trombo pequeño con la guía y el introductor.

6. Extraiga la aguja de venopunción sobre la guía con punta en J. Haga avanzar el catéter introductor de 7 French junto con su dilatador cónico sobre la guía al interior de la vena cava distal o la vena ilíaca.

NOTA: El catéter introductor tiene marcadores radiopacos para facilitar la visualización y la colocación del filtro antes de la aplicación. Los marcadores radiopacos del catéter introductor proporcionan la ubicación "elegida" entre las que se deberá colocar el filtro justo antes de retirar la vaina y aplicarlo.

7. Extraiga la guía y el dilatador dejando el catéter introductor con su punta en la vena cava distal o en la vena ilíaca. Irrigue de forma intermitente y manual o acople al catéter una infusión de goteo constante de solución salina, a fin de mantener la permeabilidad del catéter introductor.

NOTA: El cono del catéter introductor tiene un diseño interno especial. Deberá tenerse cuidado para realizar las conexiones con seguridad, pero sin ejercer una fuerza excesiva para no romper el cono.

8. Realice un venograma inferior estándar (normalmente con 25 ml de medio de contraste y 15 ml/seg). Compruebe si existe algún trombo en la vena cava, la posición de las venas renales y las anomalías congénitas. Esta es el momento para la colocación del filtro y mida el diámetro de la vena cava inferior corregido para la ampliación (normalmente un 20%).

5 Haga avanzar el catéter introductor hasta el sitio elegido con control fluoroscópico. Deberán utilizarse anticoagulantes para facilitar esta operación. Para la inserción femoral, la punta del catéter introductor debería estar 1 cm por debajo de la vena renal inferior.

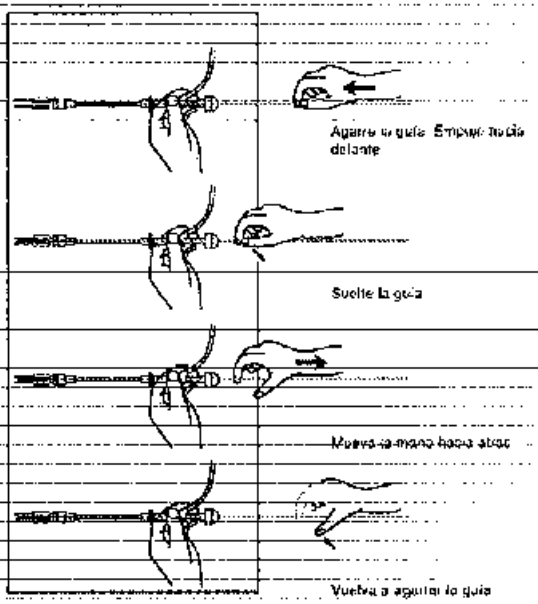
10 Extraiga el tubo y el sistema de liberación del filtro.

11 Conecte una bolsa de 500 ml de solución salina con el orificio lateral del adaptador en Y y llénelo de equipo de infusión de gotas estándar. Permita que la infusión de solución salina drene a través del tubo de almacenamiento durante 5 segundos a fin de ahuecarlo para su paso a través del catéter introductor. Ajuste el equipo de infusión para proporcionar una velocidad de goteo rápida. Aunque la bomba de presión Touhy-Borst a fin de reducir al mínimo el reflujo de la solución salina, para así impedir que la guía impulsora se pegue lateralmente.

NOTA: Es muy importante mantener la permeabilidad del catéter introductor irrigándolo con solución salina para que el segmento torcido que sujeta y orienta de forma correcta los polos del filtro no se obstruya con coágulos. Esto interfiere con la liberación del filtro.

12 Coloque el extremo libre del tubo de almacenamiento del filtro directamente en el catéter introductor que ya se encuentra dentro de la vena, permitiendo que la solución salina fluya a través de la vena durante algunos segundos. El catéter introductor y el sistema de liberación del filtro deben sujetarse en forma recta para minimizar la fricción.

Avance del filtro, ilustrado



13 Haga avanzar el filtro moviendo hacia delante la guía impulsora de nitinol a través del catéter introductor, avanzando el filtro con cada movimiento hacia delante de la guía impulsora (Figuras B-E). No retraiga la guía impulsora, únicamente haga avanzar la guía impulsora hacia delante. Para mayor comodidad del médico, se puede hacer un lazo en la guía impulsora sin producir ningún acodamiento en el material de nitinol, a fin de facilitar el manejo y avance de la guía impulsora.

14 Continúe el movimiento hacia delante de la guía impulsora hasta que la punta del filtro sobrepase el marcador radiopaco del extremo distal del catéter introductor. Llegado este momento, el mango de la guía impulsora debería estar adyacente al adaptador en Y.

Liberación/Aplicación del filtro

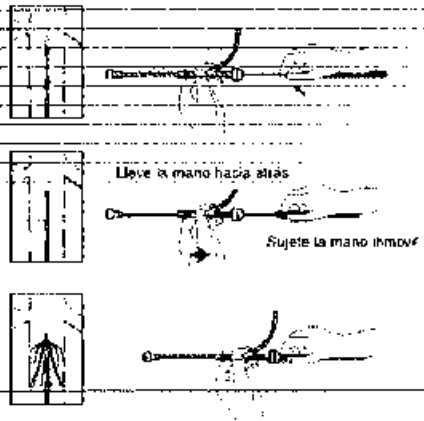
15 Aplique y libere el filtro como se describe a continuación:

Figura F: Sujete firmemente el mango de la guía impulsora.

Figura F-1: Filtro colocado en el catéter introductor justo por encima del polo superior en la vena cava inferior.

NOTA: No agarre el filtro empujando hasta el final del catéter introductor. En vez de esto, retire la vaina del filtro mientras mantiene el catéter introductor firmemente colocado a continuación.

Liberación del filtro, ilustrado



Ahora libere el filtro soltando la vaina en la vena cava inferior de la siguiente manera:

Coloque la punta del filtro-1 cm por debajo de la vena renal inferior.

Figura G: Con una mano inmóvil, la otra mano tira hacia atrás del adaptador en Y y del tubo de almacenamiento por completo sobre el mango, dejando el filtro al descubierto y liberándolo.

Figura G-1: Liberación de la vaina del filtro en la vena cava inferior.

Figura H: Colocación de las manos al finalizar el procedimiento de retirar la vaina.

Figura H-1: Filtro desplegado en la vena cava inferior.

16 Ahora extraiga la guía impulsora hacia el tubo de almacenamiento sujetando firmemente el adaptador en Y, el tubo de almacenamiento y el catéter de liberación y tirando hacia atrás de la guía impulsora.

17 Aspire el segmento del tubo de almacenamiento con una jeringa de 60 cc llena de solución salina para asegurar la permeabilidad del catéter introductor.

Venograma de seguimiento

18 Puede efectuarse un venograma de seguimiento tras colocar el catéter introductor en la vena cava inferior a través del sitio de acceso a 15 cm (grupo 1952).

19 Retire el catéter introductor y aplique compresión manual sobre el lugar de la punción de la forma usual hasta conseguir la hemostasia.

PROCEDIMIENTO OPCIONAL PARA LA EXTRACCIÓN DEL FILTRO:

ADVERTENCIA: Se recomienda encarecidamente realizar la extracción del Filtro Recovery utilizando únicamente el Recovery Cone.

Extracción del Filtro Recovery

Equipo necesario

Se necesita el siguiente equipo para el filtro:

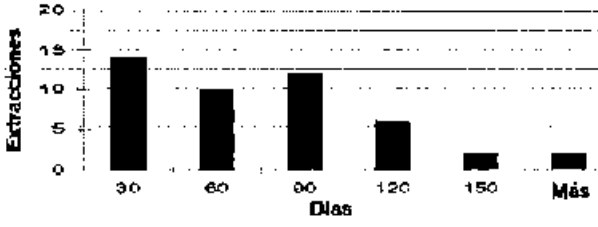
- Un sistema de extracción Recovery Cone que contenga:
  - –Una vaina de aplicación de 0.1 10 in., 75 cm y un equipo dilatador
  - –Un adaptador en Y con el Recovery Cone y un sistema impulsor de liberación
- Guía con punta en J de 0.035", 3 mm de 110 cm de longitud o más
- Aguja introductora de calibre 18
- Dilatador de 12 Fr
- Solución salina
- Tubo de extensión estéril para bolsa de solución salina o jeringa para la infusión de solución salina
- Todos los materiales básicos para la venopunción: escalpelo, cuchilla del nº 11, anestesia local, paños, etc.

Experiencia clínica

El Filtro Recovery ha sido utilizado en Canadá por un solo investigador y dos colegas en 6 hospitales en el área de Toronto con 58 pacientes, conforme a las Directrices de Acceso Especial.

Aunque en cada caso sólo un médico utilizó el dispositivo, la extracción requirió 3 médicos y varios pares de pinzas y equipo de imagen diferentes.

De los 58 filtros implantados, se han extraído un total de 46, 8 permanecen en su lugar y 4 pacientes han fallecido con los filtros colocados, por causas no relacionadas con la colocación o extracción de los mismos (paro cardíaco, cáncer, pulmonía y aneurisma pulmonar, e infarto cerebral hemorrágico). El tiempo hasta la extracción varió entre 1 y 161 días, con un promedio de 50 días (vease el histograma).



El seguimiento tras la extracción ha sido de un promedio de 305 días (entre 1 y 901 días). La mayoría de los filtros (n=43) se extrajeron por la vena yugular interna derecha, pero algunos se extrajeron a través de la vena yugular interna izquierda (n=1) y una vena colateral (n=1). Uno se extrajo quirúrgicamente durante una operación de cáncer, donde la masa interfería con el filtro. Para la extracción del filtro, se utilizaron los dos métodos descritos en las instrucciones de empleo, excepto en 4 casos, donde se utilizó una vaina más grande, o se intentó utilizar un lazo en vez de utilizar el Sistema Recovery Cone. Hubo un caso de embolia pulmonar asintomática relacionada con la vaina más grande.

El único otro evento adverso que se comunicó fue una rotura del gancho y del brazo del filtro, pero esto se debió de forma inferencial en una mujer embarazada durante el tercer trimestre de gestación al nivel L1-L2. Se desconoce si los ganchos se soldaron a tensiones débiles al parto y a la colocación de forma inadecuada que causaron una separación parcial y el alojamiento del gancho en el tejido óseo de las vértebras. El filtro se extrajo, sin el gancho.

Tabla resumen de la experiencia clínica	
Filtros Recovery implantados	58
Extracciones percutáneas de los filtros	45
Extracciones quirúrgicas de los filtros	1 (Concurrente con la resección tumoral)
Edad del paciente	8-86 años (media de 42 años)
Razón para la colocación del filtro	
Contraindicación a la anticoagulación	48
Complicaciones asociadas a la anticoagulación	10
Fracaso de la anticoagulación	5
Profilaxis	2
Tiempo hasta la extracción	1-161 días (promedio de 50 días)
Seguimiento tras la extracción	1-901 días (promedio de 305)
Complicaciones en la extracción del filtro	
Técnicas	0
Rotura del gancho secundaria a tensiones débiles a las contracciones y al parto y la colocación inadecuada	1
Embolia pulmonar asintomática tras la extracción	1

Instrucciones del procedimiento

Inserción del catéter introductor

1. Seleccione una vía de acceso venoso yugular apropiada, bien sea en el lado derecho o izquierdo dependiendo del tamaño y anatomía del paciente, de la preferencia del cirujano o de la ubicación de la trombosis venosa.
2. Prepare, anestesie, punce, canalice y asegure el lugar de punción en la piel de la forma convencional.
3. Seleccione y abra el envase del catéter ***Recovery Cone***. Abra el envase del Kit A Catéter Introductor.
4. Corte ligeramente la piel con una cuchilla del nº 11 y realice una venopunción con una aguja estándar a través del catéter 18.
5. Inserte la guía y hágala avanzar suavemente al lugar donde se encuentra el Filtro ***Recovery*** a colocar.
6. Extraiga la aguja de introducción sobre la guía.
7. Dilate progresivamente el trayecto que se ha realizado al acceso con un dilatador de 12 Fr.
8. Haga avanzar el catéter introductor de modo gentil sobre el dilatador cónico sobre la guía anterior de la vena.

NOTA: El catéter introductor tiene un marcador radiopaco en la extremidad distal de la vaina del catéter para facilitar la visualización.

9. Extraiga la guía y el dilatador de modo a catéter introductor con su punta en el lugar apropiado. Irrigue de forma intermitente a mano o acople al catéter una infusión de goteo constante de solución salina, a fin de mantener la permeabilidad del catéter introductor.
10. Realice un venograma para localizar exactamente la(s) vena(s) ilíaca(s) común(es) y la(s) cava(s). Compruebe si existe algún trombo en el filtro. Si hay una cantidad importante de trombo dentro del filtro, no avance el Filtro ***Recovery***.

Inserción y ubicación del Recovery Cone

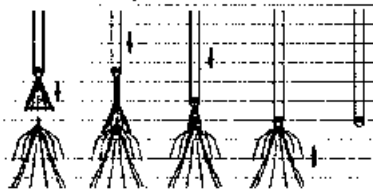
11. Extraiga el sistema expulsor y el cono de Kit B.
12. Irrigue la luz/lumen central del catéter del cono y humedezca el botón con 0,9% salina, preferentemente solución salina heparinizada.
13. Retraiga completamente el ***Recovery Cone*** hacia el adaptador en Y para plegar el cono.

NOTA: El cono debe estar totalmente retraído en el adaptador en Y antes de conectar el sistema al catéter introductor a fin de asegurar que pueda liberarse el cono a través del catéter con facilidad.

14. Conecte una bolsa de 500 ml de solución salina o una jeringa con solución salina en el orificio lateral del adaptador en Y. Permita que la infusión de solución salina circule a través del cono de extracción en el adaptador en Y durante 5 segundos aproximadamente apretando la válvula del adaptador Touhy-Borst a fin de reducir al mínimo el reflujo de la solución salina hasta el alimentador, pero empuje para que el eje impulsor avance libremente.
15. Acople directamente el catéter introductor al extremo macho del adaptador en Y con el cono plegado. El catéter introductor y el sistema de liberación del filtro deben quedarse en línea recta para mantener la inclinación.
16. Haga avanzar el cono suavemente hacia delante al eje impulsor a través del catéter introductor, avanzando el cono con cada movimiento hacia delante del eje impulsor.
17. Continúe el movimiento hacia delante de la guía expulsora hasta que el cono radiopaco del extremo distal del catéter introductor. Quite la vaina para abrir el cono, estabilizando el eje y retrayendo el catéter.

Captura del Filtro *Recovery*

Extracción del filtro, ilustrado



18. En las Figuras B-F aparece ilustrada la captura del Filtro ***Recovery***.

Figura B: Después de haberse abierto el cono por encima del filtro, avance el cono sobre la punta del filtro, sujetando el catéter introductor sin moverlo y avanzando el eje impulsor. Se recomienda obtener una imagen fluoroscópica anteroposterior para confirmar que el cono está por encima de la punta del filtro.

Figura C: Cierre el cono sobre la punta del filtro avanzando el catéter introductor sobre el cono mientras mantiene inmóvil el eje impulsor.

Figura D: Continúe haciendo avanzar el catéter introductor sobre el cono hasta que el cono se enganche dentro del catéter introductor.

Figura E: Con el cono plegado sobre el filtro, extraiga el filtro estabilizando el catéter introductor y retrayendo el eje impulsor en un solo movimiento suave y continuo.

Figura F: Se ha retirado el filtro en el catéter.

Venograma de seguimiento

19. Puede efectuarse un venograma de seguimiento tras extraer el catéter introductor (aproximadamente 30 ml de medio de contraste a 15 ml/segundo).
20. Retire el catéter introductor y aplique compresión manual sobre el lugar de la punción, de la forma usual para conseguir la hemostasis.

Técnica asistida con guía

Debido a las diferencias anatómicas con respecto a la punción del Filtro ***Recovery***, puede utilizarse técnicas asistidas con guía.

Uso de la guía

Si resulta difícil avanzar el cono sobre la punta del Filtro ***Recovery***, se puede utilizar una guía para facilitar el avance del cono sobre la punta del filtro.

Retire la vaina introductora y el eje del cono de la punta del filtro. Inserte una guía de 0,035" a través del lumen central (punta en J o angulada; se recomienda una guía con revestimiento hidrofílico). Haga avanzar la guía a través del cono y a través del filtro hasta la punta.

Una vez confirmado que la guía está en contacto o cerca de la punta del filtro, avance el cono sobre la guía hasta la punta del filtro.

Haga avanzar la vaina introductora para plegar ligeramente el cono sobre la punta del filtro. Retire la guía en el eje impulsor.

Continúe con la extracción del filtro como se describe en el paso 16.

J. Forma de suministro

Cada Filtro ***Recovery*** se suministra previamente cargado en el tubo de almacenamiento. Cada Filtro ***Recovery*** es estéril y no pirógeno, a menos que el envase esté abierto o dañado, y está listo para un solo uso. El tubo de almacenamiento y el sistema de liberación están premontados. Si el filtro se libera de forma inadvertida, no intente reesterilizarlo ni recargarlo.

Nota: Después del uso, los accesorios del Filtro ***Recovery*** y los elementos de sujeción pueden ser un peligro biológico potencial. Manipúlelos y deséchelos según la práctica médica aceptable y conforme a las leyes y normas locales, estatales y federales aplicables.

El Filtro ***Recovery*** debería guardarse en un lugar fresco (a temperatura ambiente) y seco.

K. Garantía

Bard garantiza al primer comprador que este producto estará exento de defectos en los materiales y de fabricación durante un período de 2 años desde la fecha de la primera compra. La responsabilidad derivada de la garantía limitada de este producto se limitará a la reparación o sustitución del producto defectuoso, sólo a discreción de Bard, o el reembolso del precio pagado. Esta garantía limitada no cubre el desgaste debido al uso o los defectos que pudieran surgir debido al mal uso del producto.

EN LA MEDIDA PERMITIDA POR LA LEGISLACIÓN APLICABLE, ESTA GARANTÍA LIMITADA DE PRODUCTO REEMPLAZA TODAS LAS DEMÁS GARANTÍAS EXPRESAS O IMPLÍCITAS, INCLUYENDO, AUNQUE NO DE FORMA EXCLUSIVA, CUALQUIER GARANTÍA DE COMERCIABILIDAD O IDONEIDAD PARA UNA FINALIDAD CONCRETA. EN NINGÚN CASO BARD SE RESPONSABILIZARÁ DE DAÑOS EMERGENTES O CONTINGENTES RESULTANTES DE LA MANIPULACIÓN O USO DE ESTE PRODUCTO.

Algunos países no permiten la exclusión de garantías implícitas, o los daños emergentes o contingentes, de modo que tales limitaciones o exclusiones quizá no le apliquen en la legislación de su propio país.

Fecha de emisión de la etiqueta: 12/03

En caso de que haya transcurrido 2 años entre esta fecha y el momento de utilizar el producto, el usuario debe dirigirse a C.R. Bard para obtener información adicional sobre el producto.

Bard, Recovery y *Recovery Cone* son marcas comerciales registradas de C.R. Bard, Inc. o de una filial.

Patentes bardianas canadienses 1,007,358 y 6,258,026. Otras patentes pendientes.

Bibliografía:

1. "ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism" 2000 (Rev.12), Effective 01/01/01

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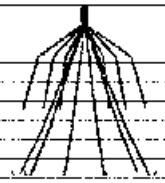
Recovery® Filter Systeem voor gebruik in de vena cava



NEDERLANDS

Gebruiksaanwijzing

Opgepast: De federale wetgeving van de Verenigde Staten bepaalt dat dit product slechts door of op voorschrift van een arts mag worden verkocht.

A. Algemene informatie

Het *Recovery* filter representeert een nieuwe generatie van veneuze onderscheppingshulpmiddelen die bedoeld zijn om longembolieën te voorkomen. Het unieke ontwerp en materiaal van het *Recovery* filter bieden een uitstekende liersprotheticiteit en maken percutane plaatsing via een standaard angiografische inbrenguis met een inwendige diameter van Ch. 7 mogelijk, met minimale problemen op de inbrengplaats. De plaatsingsprocedure is eenvoudig en eenvoudig uit te voeren.

De femoraltoegang is bedoeld om door een 40 cm lange inbrengkatheter met een inwendige diameter van Ch. 7 te worden opgevoerd met behulp van een flexibele leidraad doordraad. Een tussenstuk aan het einde van de draad is ontworpen om de punt van het filter voor te duwen en een gegeefd deel is ontworpen om de filterpoten te vatten en in de juiste positie te houden. Deze onderdelen houden het filter vast op de draad terwijl deze het filter met de punt eerst opvoert naar het uiteinde van de sublector, die onder de juiste anatomische omstandigheden op de vena cava inferior is geplaatst. Als de tip van het filter op de inbrengkatheter rust, zal het filter worden gepositioneerd tussen de radio-opake markeringen op de inbrengkatheter. De inbrengkatheter en de inbrengstijfmiddelen worden dan teruggetrokken op het handvat van de doordraad en het filter uit de huis te maken en het de kans te geven zich vrijwel bijnaakte vorm aan te nemen. Het verwijdersysteem maakt het mogelijk het *Recovery* filter meer een geoptimaliseerde tip te plaatsen en voorkomt dat de poten elkaar kruisen.

Het *Recovery* filter is bedoeld als een permanent filter. Als de klinisch geïndiceerd is, kan het *Recovery* filter op bepaalde wijzen worden verwijderd volgens de instructies gegeven onder Optionele verwijderingsprocedure. De elastische kenmerken van het *Recovery* filter maken dat het filter zich in een verkleinde toestand kan aanpassen, maar bij percutane verwijdering vervormde of elastische vlijt. (Zie Optionele verwijderingsprocedure voor specifieke verwijderinstructies).

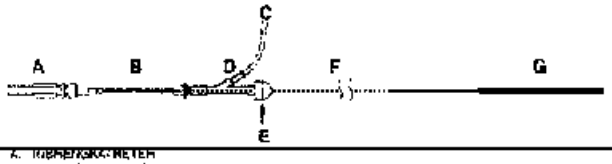
Gevaren met MRI: Het *Recovery* filter implantaat is veilig bij gebruik van MRI in situ onder de volgende voorwaarden. Het wordt niet door de werking van het apparaat verhoogd.

B. Beschrijving van het hulpmiddel

Het *Recovery* filter systeem bestaat uit het filter en het inbrengsysteem. Het *Recovery* filter bestaat uit zeven draden van nitinol gemaakt, die uit een centrale nitinol huis steken. Deze bevatten vormen twee niveaus van ankerhaken die poten vormen het laagste niveau en de 4 vormen het hoogste niveau. Het *Recovery* filter is bedoeld voor gebruik in de vena cava met een maximale diameter van 28 mm.

Het *Recovery* filter inbrengsysteem is afgebeeld in Figuur A. het inbrengsysteem bestaat uit: een inbrengbuis met diameter Ch. 7 inwendige diameter (ID), het *Recovery* filter, een opslagbuis met een ingang voor het laten stromen van fysiologische zoutoplossing, en een duwsysteem. Het *Recovery* filter wordt verpakt in de voorgeladen inbrengopslagbuis geleverd.

Figuur A. Recovery filter systeem



A. INBRENGKATHETER
B. OPSLAGBUIS FILTER
C. INBRENGSYSTEEM MET FLUOROSCOPISCH ZOOM
D. ZIJDELINGSE OPENING
E. VERSTELBARE TOUHY-BOREST ADAPTER
F. NITINOL DUWSTAAFJE
G. HANDVAT DRAADLAD

BELANGRIJK: Lees de aanwijzingen zorgvuldig voor u het *Recovery* filter gebruikt.

C. Indicaties

Het *Recovery* filter systeem is geïndiceerd voor gebruik bij personen van bomb de longembolieën door middel van percutane plaatsing in de vena cava in de volgende situaties:

- Trombo-embolie van de longen bij bestaande contra-indicaties tegen antistollingsmiddelen
- Falen van antistollingsbehandeling bij trombo-embolieën
- Als voorbehandeling na een grote longembolie als de te verwachten voordelen van conventionele behandeling gering zijn.
- Chronische, herhaalde longembolieën als antistollingsbehandeling heeft gefaald of gecontra-indiceerd is.

Het *Recovery* filter kan worden verwijderd volgens de instructies die hieronder worden aangegeven en het hoofdstuk getiteld Optionele Procedure voor Filterverwijdering.

D. Contra-Indicaties

OPGEPAST: Als de gecorrigeerde diameter van de vena cava inferior (VCI) meer dan 28 mm is mag het filter niet in de VCI worden ingebracht.

Het *Recovery* filter mag niet worden geïmplanteerd bij:

- Zwangere patiënten bij wie dosering dodelijk kan schaden. De risico's en voordelen moeten zorgvuldig worden afgewogen.
- Patiënten met een diameter van de vena cava van meer dan 28 mm
- Patiënten die eerst lijden op een septische embolie.

E. Waarschuwingen

Implantatie van het *Recovery* filter

1. Het *Recovery* filter voor de vena cava wordt opgelegen in de veneuze en arteriële bedoeld voor eenmalig gebruik. Het het laten met uit de opslagbuis voor het gepositioneerd in de vena cava, aangezien het *Recovery* filter niet nauwkeurig kan worden herladen in de opslagbuis.
2. Bij het inbrengen van het *Recovery* filter door de inbrengbuis mag alleen in voorwaartse richting aan de bewegen. Het terugtrekken van de draad naar de inbrengbuis kan leiden tot van zijn plaats raken van het filter, het knikken van poten of samen van het filter, en kan het eenvoudig maken het filter binnen de huis nog verder op te voeren.
3. Het *Recovery* filter systeem is uitsluitend ontworpen om via de femoralis te worden ingebracht. Breng het *Recovery* filter met inbrengsysteem nooit van bovenaf in via de vv. jugulares, subclavia of antecubiti, aangezien dit zal leiden tot een onjuiste oriëntatie van het *Recovery* filter en de vena cava inferior.
4. Als er op de röntgenfoto's inbrengplaats een grote bomtus wordt aangetoond, breng dan met het filter terugtrekken aan de inbrengen. Probeer het filter niet in een trombus te brengen. Een kleine bomtus kan met door de voerdraad en de inbrengbuis worden omsloten.
5. Gebruik voorbij voorgaan van het *Recovery* filter alleen met *Recovery Cone* verwijderingssysteem. Gebruik een andere filterverwijderingssysteem.
6. Voer de voerdraad of de inbrengkatheter niet op een manier dat het filter mogelijk kan worden beschadigd.

Verwijdering van het *Recovery* filter

1. Trek niet het *Recovery* filter te verwijderen als er significante hoeveelheden trombus in het filter zijn gevangen of als de ly van het filter zich in de wand van de vena cava heeft vastgezet.
2. Gebruik voor het verwijderen van het *Recovery* filter alleen het filter overy *Cone* verwijderingssysteem. Gebruik een andere verwijderingssysteem kan leiden tot letsel. Het gebruik van andere hulpmiddelen dan het in het verwijder gelei dit kan resulteren in longembolieën.

F. Voorzorgen

Implantatie van het *Recovery* filter

1. Bij aanwezigheid van vocht in de inbrengkatheter dient het filter te worden geïnstalleerd voordat de inbrengkatheter wordt ingebracht.
2. Anatomische variaties kunnen het inbrengen en aanbrengen van het filter bemoeilijken. Het zorgvuldig volgen van deze gebruiksaanwijzing kan de duur van het inbrengen verkorten en de kans op problemen verkleinen.
3. Vergewis u ervan dat de vena cava inferior geschikt is voor de implantatie voordat u de patiënten met een significante kyfoscoliotische vervorming van de wervelkolom en/of de vena cava inferior de richting van een dergelijke malformatie vaak volgt. Hierdoor kan percutane verwijdering van het filter lastiger worden.

Verwijdering van het *Recovery* filter

1. Anatomische variaties kunnen het inbrengen en het gebruik van het *Recovery* *Cone* verwijderingssysteem compliceren. Het zorgvuldig volgen van deze gebruiksaanwijzing kan de duur van het inbrengen verkorten en de kans op problemen verkleinen.
2. Vergewis u ervan dat de wervelkolom niet significant voorbij te zijn als u verwijdering van het *Recovery* filter met het *Recovery Cone* verwijderingssysteem overweegt bij patiënten met een significante kyfoscoliotische vervorming van de wervelkolom en/of de v. cava inferior de richting van een dergelijke malformatie vaak volgt. Hierdoor kan percutane verwijdering van het filter lastiger worden.

G. Potentiële Complicaties

Migratie van het filter. De kan worden veroorzaakt door plaatsing in een te wijde vena cava met een diameter van meer dan 28 mm, of als de juiste verankeringstechnieken niet zijn gebruikt.

Perforatie van de wand van de vena cava. Dit kan voorkomen als de punt van inbrengkatheter niet ovdit gevolgd.

Occlusie van de vena cava. De kans dat de opnieuw dient te worden ingebracht, liggen de algemene kans van de risico's en de voordelen bij een patiënt met longembolie, of een patiënt die deze zonder interventie grote kans op heeft.

H. Benodigde apparatuur

De volgende apparatuur wordt benodigd:

Een *Recovery* filter met inbrengsysteem dat bestaat

- Een 40 cm lange, Ch. 7 ID inbrengbuis met dilatator set
- Een opslagbuis met vooraf geladen *Recovery* filter en inbrengsysteem met duwstaaf
- 0,96 mm (0.038 inch) Voerdraad met 3 mm J-tip, lengte minimaal 180cm
- Inbrengnaald nr 18
- Fysiologische zoutoplossing
- Steriele aanspoeling voor hydrofiele zout- of de urinus
- Basismateriaal voor het aanprikken van de vena, scalpel met mesje nr 11, lokaal anesthetica, (Xylocaïnestof, etc
- Een toegangset bestaande uit een 0,96 mm (0.038 inch) voerdraad met 3 mm J-tip aanprikmaald, scalpel nr. 11, en 10ml spuit is te verkrijgen bij C. R. Bard, catalogusnummer 4400E

Als de sets zoals hier en het *Recovery* filter percutaan is verwijderen kan het *Recovery Cone* verwijderingssysteem worden aangeschaft bij C.R. Bard, nr:

I. Gebruiksaanwijzing

Inbrengen van de inbrengkatheter Ch. 7 ID en voorbereidende angiografie

1. Kies een geschikte femorale toegangsplaats, aan de linker of de rechter kant, afhankelijk van de grootte en de anatomie van de patiënt, de voorkeur van de operateur of de plaats van de vroegere littekens.
2. Desinfecteer, dek af en verdoof de huid bij de inbrengplaats op de gebruikelijke wijze.
3. Neem het filterpak en open dit. Haak aan A open - de verpakking van de inbrengkatheter.
4. Steng een kleine incisie in de huid aan met het mesje nr 11 ter plaats van het gekozen inbrengpunt.
5. Steng de J-voerdraad in en voer deze voorzichtig op tot in de distale vena cava of de vena iliaca.

OPMERKING: Als bij het inbrengen via de v. femoralis weerstand wordt gevoeld, moet u de voerdraad terugtrekken en door middel van kleine injectie van contrastvloeistof onder doorlichting controleren dat de vene doorgankelijk is. Als er een grote trombus wordt aangetroond, de aanprikwand verwijderen en de vene aan de andere kant proberen. Een kleine trombus kan met door de voerdraad en de inbrengbuis worden omsloten.

6. Verwijder de aanprikmaald over de J-voerdraad. Voer de Ch. 7 dilator met tapse dilatator over de voerdraad en de distale vena cava of in de v. iliaca.

OPMERKING: De inbrengkatheter heeft radio-opake markeringen om te helpen bij de visualisatie en het positioneren van het filter voor het plaatsen. De radio-opake markeringen op de inbrengkatheter geven de 'doorlaatlijn' aan waarbinnen het filter moet worden gepositioneerd met voor het terugtrekken van de huis en het plaatsen.

7. Verwijder de voerdraad en de dilatator, waarbij de inbrengkatheter met de tip in de distale vena cava of vena iliaca blijft liggen. Spoel de katheter met gehepariniseerde fysiologische zoutoplossing handmatig door of sluit een infuus met fysiologisch zout aan om de inbrengkatheter open te houden.

OPMERKING: De aansluitconnector van de inbrengkatheter heeft een speciaal inwendig ontwerp. U moet oppassen dat verbindingen stevig worden gemaakt, maar zonder overmatige kracht, waardoor breuk in het aansluitstuk kan optreden.

8. Verwijder een standaard voerdraad met angiografie (bijvoorbeeld 0,96 cm (0.038 inch) contrastmiddel nodig bij 15 ml/s). Let op tijdens dit de v. cava, de positie van de ankerhaken en controleer de afwijkingen. Kies het optimale niveau voor plaatsing van het filter en meet de diameter van de vena cava ter plaatse, vastgelegd voor de volgende stappen (in bijzondere gevallen 28 %).
9. Schuif de inbrengkatheter op tot aan het gekozen niveau van de doorlichting. De voerdraad en de dilatator moeten opnieuw worden ingebracht om de gewenste positie te handhaven. De inbrengkatheter moet de tip in de distale vena cava of onder de laagste nierader blijven.

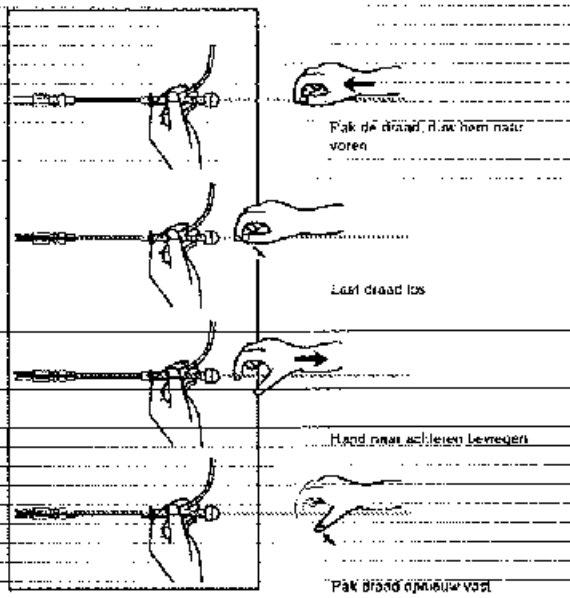
10 Neem het filter met introducersysteem uit set B

11. Sluit een 500 ml zak fysiologisch zout aan op de zijarm van het Y-adapter door middel van een standaard infuusset. Laat de fysiologisch zout oplossing gedurende 5 seconden lopen het filter te vullen om de lucht te maken voor het passeren van de introducerkatheter. Sluit de infuusset af op een snelle drukpreventie. Draai de "Duty-Boss" compressietap aan om zo weinig mogelijk lucht van fysiologisch zout te geven zonder de diameter de draad aan mogelijke kan worden opgevoerd

OPMERKING: Het is heel belangrijk om de doorgankelijkheid van de introducerkatheter in stand te houden door spoelen met fysiologisch zout totdat het gedeelte segment dat de filterpoten vat en enkele houdt niet door elkaar wordt bedekt. En voor het aanbrengen van het filter beëindigen.

12. Bevestig het open uiteinde van de opvoerbuis van het filter-draad op de introducerkatheter die klikt in de vena cava inferior (VCI) door de fysiologische zoutoplossing gedurende enige seconden in de vena cava inferior te laten. De introducerkatheter en introducersysteem moeten op een zodanige manier liggen om zo weinig mogelijk vervorming te genereren

Illustratie opvoeren van het filter



13. Voor het filter op zijn plaats draad naar voren te duwen door de introducerkatheter, waarbij u het filter met iedere voorwaartse beweging verder opschuift (fig. B-E). Trek de draad niet terug, beweeg de draad alleen in voorwaartse richting. Voor het gemak van de operateur kan de draad in een lus worden gelegd, zonder het introducerset te buigen, om de draad gemakkelijker te kunnen blokkeren en opvoeren.

14. Ga door met de voorwaartse beweging van de draad totdat de filterpunt bij de radio-opake markering van het distale einde van de introducerkatheter ligt. Op dit punt moet het handvat van de draad naast het Y-aansluitstuk liggen

Vrijgeven/terugbrengen van het filter

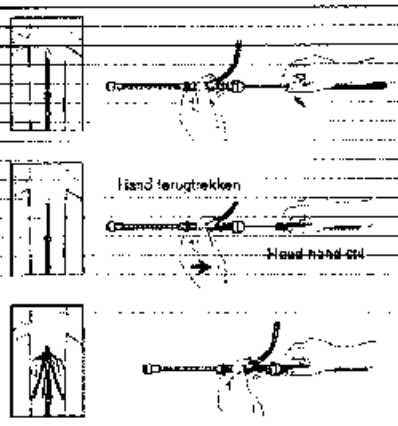
15 Breng het filter aan en geef het vrij als hieronder beschreven:

Figuur F: Handvat van draad stevig vasthouden.

Figuur F-1: Filter voor plaatsing gepositioneerd in introducerkatheter tussen de radio-opake markeringen voor het aanbrengen in de vena cava inferior.

OPMERKING: Filter niet aanbrengen door het voorbij het uiteinde van de introducerkatheter te duwen. Verwijder in plaats daarvan de huls van het uitstekende filter door de introducerkatheter terug te trekken zoals hieronder beschreven.

Filter Release, Illustrated



Maak nu het filter vrij door het als volgt in de vena cava inferior uit de huls te halen:

Positioneer de punt van het filter 1 cm onder de laagste nierader.

FIGUUR G: Terwijl de ene hand op zijn plaats blijft, trekt de andere hand de combinatie van het Y-adapter en de opvoerbuis volledig over het handvat terug, waarbij het filter bloot komt te liggen en vrij komt.

Figuur G-1: De huls halen van het filter in de VCI

Figuur H: Positie van de handen na voltooiing van de buisverwijdering

Figuur H-1: Filter op zijn plaats in VCI

16 Trek nu de draad terug in de opvoerbuis door de combinatie van het Y-adapter, de opvoerbuis en de introducerkatheter stevig op zijn plaats te houden en aan de draad te trekken.

17 Herhaal het spoelen met fysiologisch zout om het inlaat- en de introducerkatheter doorgankelijk te houden.

Conjunctovenogram van de vena cava

18. Een controleconjunctovenogram van de vena cava kunt het doorgankelijkheid van de introducerkatheter en dus, deze wordt gebruikt te bepalen (gunstig: 30 ml contrastmiddel bij 15 ml/sec)

19. Verwijder de introducerkatheter en oefen de gebruikelijke druk uit op de venipunctieplaats om hemostase te bewerkstelligen

OPTIONELE PROCEDURE: VOOR BEHANDELING

Verwijdering van het Recovery filter

OPGEPAST: Er wordt ten sterkste aanbevolen dat het Recovery filter alleen wordt verwijderd met de Recovery Cone.

Benodigde apparatuur

De volgende apparatuur wordt benodigd:

- Een Recovery Cone verwijderingssysteem set bevat:
  - Een 75 cm lange (Ch-10-F) introducer sheath met dilator set
  - Een Y-adapter met Recovery Cone en spoel-inlaatsysteem
- Een 0.89 mm (0.035 inch) voerdraad met 3 mm J-tip, 110 cm lang
- Aanprikpistool nr. 18
- Ch-10 dilatator
- Fysiologische zoutoplossing
- Steriel aandrukdoek voor afdoen met fysiologisch zout of spuit met fysiologische zoutoplossing
- Alle basisinstrumenten voor venipunctie: scalpel met mesje nr. 11, klauw, zweet, steriel doek, afdekmaterieel, etc.

Klinische ervaring

Het Recovery filter is in Canada gebruikt voor een enkele onderzoeker met twee collega's in zes ziekenhuizen. Totaal bij 48 patiënten, onder speciale regelgeving (Special Access regulations).

Hoewel het hulpmiddel eigenlijk maar door één arts werd gebruikt, is de verwijdering uitgevoerd door drie artsen met verschillende ervaringsniveaus en beeldvormende apparatuur.

Van de 52 geïmplanteerde filters zijn er in totaal 48 met succes verwijderd. 3 blijven op hun plaats zitten, en 4 patiënten zijn niet de filters nog in situ overleden aan oorzaken die niet aan het plaatsen of verwijderen van de filters gerelateerd waren, zoals patiënten en aspergillose van de long en hemorragische beroerte. De tijd tot verwijdering bedroeg tussen 1 en 161 dagen, gemiddeld 60 dagen (zie histogram)

Bij de verwijdering duurde de filterweg gemiddeld 325 dagen (tijdrange: 1 en 901 dagen). De meeste (n=43) werden via de rechter vena jugularis interna verwijderd, maar sommige zijn via de linker vena jugularis interna (n=1) of een collateralis vena verwijderd (n=1). Een werd chirurgisch verwijderd tijdens een operatie voor kanker waarbij de massa langs het filter drukte. De twee mislukken bestonden in de gebruikelijke jong verder in alle gevallen gebruikt, op 4 na, waarbij een grotere huls werd gebruikt, of gebruikt werd gebruik te maken van een lus in plaats van het Recovery Cone verwijderingssysteem. Er was een geval van asymptomatische longembolie bij gebruik van de grotere huls

De enige ernstige geregistreerde bijwerking was een gebroken filterpoot heeft. De filter was intraveneus geplaatst bij een zwangere vrouw in het derde trimester op het niveau L1-2. De fractuur was naar men aannam het gevolg van krachten tijdens de bevalling en de inflammatie plaatsing, waardoor enkele defecte opbrachten van een wervel vastzetten, het filter werd tijdens de kraak met verwijderd

Overzichtstabel	
Klinische gegevens	
Recovery filters geïmplanteerd	52
Pogingtot verwijderingen van de filter	45
Chirurgische verwijderingen van de filter	1 (gelijktijdig met tumorresectie)
Leeftijd patiënt	8-66 jaar (gemiddeld 32 jaar)
Redenen voor filterplaatsing	
Contra-indicatie voor anticoagulatie	40
Complicaties langerwijl van anticoagulatie	10
Falen van anticoagulatie	3
Profylaxe	2
Tijdsduur tot verwijdering	1-161 dagen (gemiddeld 60 dagen)
Follow-up na verwijdering	1-901 dagen (gemiddeld 325 dagen)
Complicaties van filterverwijdering	
Technisch	0
Klinisch: terugvolgen van spanningen door buisvormen en gebroken abnormale intravenale plaatsing	1
Asymptomatische longembolie na verwijdering	1

Aanwijzingen voor de ingreep

Inbrengen van de introducerkatheter

1. Selecteer een geschikte toegangsroute tot de vena jugularis aan de linker- of rechterkant, afhankelijk van de grootte of anatomie van de patiënt, de voorkeur van de operateur of de positie van zenuwen.
2. Prepareer, bedek en verdoof de venipunctieplaats op standaard wijze.
3. Selecteer en open de Recovery Cone-katheterverpakking. Open de introducerkatheterverpakking bij A.
4. Maak een incisie in de huid met een #11 scalpelmesje en verricht de venapunctie met een 18 G aanprikpistool.

5. Breng de voerdraad en introducteur met voorzichtig op naar de Recovery filter voor de verwijdering
6. Verwijder de verwijderingsmarkering van de voerdraad
7. Draaien het inbrengmechanisme vervolgens met een tuitsleutel Ch. 12
8. Schuif de Ch. 10 inbrengkatheter samen met zijn tuitsleutel dilatator over de voerdraad in de vena

LET OP: De introductiekatheter heeft een radiopaque markeerband aan het distale uiteinde van de katheterhuis voor betere zichtbaarheid.

9. Verwijder de voerdraad en dilatator, en sluit de tip van de introductiekatheter op de gewenste plaats achter. Spoel met fysiologische oplossing of sluit een doppje van het type dat met fysiologische oplossing is gevuld. Sluit de hemostaseklep open stijl.
10. Verwerf een standaard cavogram van de v. cava inferior (30 ml contrastmiddel met een snelheid van 15 ml/sec). Controleer of het ostium acceptabel is in de filter. Verwijder de Recovery filter het nieren een beschrijving van het ostium acceptabel is in de filter.

Inbrengen en plaatsen van de Recovery Cone

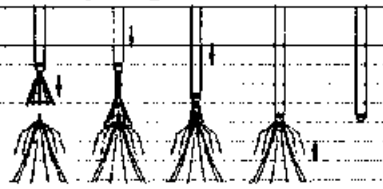
11. Haal de kegel en het opbergsysteem uit het B
12. Spoel het centrale lumen van de Ch. 10 inbrengkatheter en bevochtig de kegel met de fysiologische zoutoplossing, bij voorkeur een gesteriliseerde fysiologische zoutoplossing.
13. Trek de kegel in gestrekte toestand in de Y-adapter totdat de kegel opgevouwen is.

PAS OP: De kegel moet helemaal in de Y-adapter teruggetrokken zijn voordat het systeem aan de introductiekatheter verbonden wordt, zodat de kegel gemakkelijk geplaatst kan worden via de katheter.

14. Sluit een 500-ml zak 0,9 mm sp. f met fysiologische zoutoplossing aan op de zij-opening van het Y-stuk. Laat de fysiologische zoutoplossing gedurende 5 seconden door de verwijderingskegel stromen. Draai de Luer-Lock adapterklep aan om zo weinig mogelijk lekken van fysiologische zoutoplossing toe te laten zodat de dilatator de introductiekatheter kan worden opgevoerd
15. Verbind het mannelijke uiteinde van de Y-adapter met de inbrengkatheter. De inbrengkatheter en het inbrengsysteem moeten op een rechte lijn liggen om zo weinig mogelijk weerstand te genereren.
16. Voer de kegel op door de dilatator totdat deze enkele centimeters voorbij de inbrengkatheter is. Vervolgens de kegel met redelijke voorzichtigheid terugtrekken totdat de dilatator verder opschuift.
17. Ga door met de voorwaartse beweging van de dilatator tot de zwarte band op de kegel op de radiopaque markering past in de distale opening van de inbrengkatheter ligt. Houd de kegel vast en niet te voorzichtig om de schacht vast te houden en de katheter terug te trekken.

Verwijderen van het Recovery filter

Illustratie verwijdering filter



18. Het terugtrekken van het Recovery filter wordt getoond in de figuren B-F:

Figuur B: Houd de kegel boven het filter en geopend, schuif u de kegel over de punt van het filter door de inbrengkatheter te houden en de dilatator op te roepen. Aanbevolen wordt een dalende inbrengsysteem schuin van voren te maken om te bewegen dat de kegel over de filterpunt ligt.

Figure C: Sluit de kegel over de filterpunt door de inbrengkatheter over de kegel op te voeren terwijl de dilatator op dezelfde plaats houd.

Figure D: Blijf de inbrengkatheter over de kegel schuiven tot de kegel zich in de inbrengkatheter bevindt.

Figure E: Nu de kegel over het filter is dichtgevouwen, verwijdert u het filter door de inbrengkatheter vast te houden en de dilatator in een langzame continue beweging terug te trekken.

Figure F: Het filter is in de katheter teruggetrokken.

Contrastcavogram van de v. cava

19. Een contrastcavogram van de v. cava kan worden gemaakt na het terugtrekken van de inbrengkatheter (in typische gevallen 30 ml contrastmiddel bij 15 ml/sec).
20. Aanpassingen van de inbrengkatheter en/of de gebruikelijke dilatator uit op de verwijderingsplaats om herpositie te bewerkstelligen

Techniek met behulp van een voerdraad

Deze alternatieve variatie in de positionering van het Recovery filter kunnen technieken met gebruik van een voerdraad nodig zijn.

Gebruik van een voerdraad

Als het nodig is om de kegel over de punt van het Recovery filter te schuiven, kan een voerdraad worden gebruikt om de geleidedraad en van de kegel over de filterpunt te vergemakkelijken:

Trek de inbrengkatheter en de kegel weg van de filterpunt. Breng een 0,89 mm (0.035 inch) voerdraad in door het centrale lumen (met 3 cc of gemeld op een met hydrofiel materiaal gecoate voerdraad wordt aanbevolen). Schuif de voerdraad op door de kegel en door het filter totdat de filterpunt.

Als bevestigd dat de voerdraad langer de filterpunt ligt of door middel van kegel over de voerdraad op te voeren tot aan de filterpunt. Voer de inbrengkatheter en de kegel iets over de filterpunt samen te voeren. Trek de voerdraad terug in de schacht van de geleider.

Ga verder met het verwijderen van het filter zoals aangegeven in stap 15.

J. Conclusie

Uw **Recovery** filter wordt een zeer geschikte voorgeboden gekeerd. Uw de **Recovery** filter is correct en psychologisch correct als de verwijdering is gepland of beschadigd en is gereed voor eindelijk gebruik. De opslagtijd en het inbrengsysteem zijn vooral als deze gereed. Als het filter onbedoeld migreert, probeer dan niet het ostium te identificeren of opnieuw te laden.

Opmerking: Als gebruik kunnen de accessoires en inbrengsystemen van het **Recovery** filter een potentiaal beschadigingsgevaar vormen. Behandel ze en werp ze weg op medisch geaccepteerde wijze en volgens de geldende plaatselijke en landelijke wetten en regels.

Het **Recovery** filter dient het (bij herhaaldelijk gebruik) en op een enkele plaats te worden bewaard.

K. Garantie

Bard garandeert aan de eerste koper van dit product dat dit product vrij is van fouten in materiaal en vervaardiging gedurende een periode van één jaar na de eerste aankoop, en de mogelijkheid tot hiervan onder deze beperkte productgarantie blijft beperkt tot reparatie of vervanging van het defecte product, dit wordt tijdens de beoordeling van Bard Vascular, of terugbetaling van de aankoopprijs. Schade van dit product als gevolg van nalatigheid, of defecten als gevolg van verkeerd gebruik vallen niet onder deze beperkte garantie.

IN DE MATE WAARIN HET GELDENDE RECHT DIT TOELAAT VERVANGT DEZE BEPERKTE PRODUCTGARANTIE ALLE ANDERE GARANTIES, EXPLICIET OF IMPLICIET, WAARONDER, MAAR NIET BEPERKT TOT, IEDERE GARANTIE VAN VERKOOPBAARHEID OF GESCHIKTHEID VOOR EEN BEPAALD DOEL. BARD ZAL IN GEEN GEVAL VERANTWOORDELIJK ZIJN VOOR ENIGE INCIDENTELE OF GEVOLGSCHADE DIE HET GEVOLG IS VAN UW GEBRUIK VAN OF OMGANG MET DIT PRODUCT.

Bepaalde staten binden al een geen uitsluiting van impliciete garantie en van incidentele of gevolgschades toe. U heeft in deze staten de rechten die in uw plaatselijke wetten en andere juridische stappen te ondernemen.

Digitale datum label: 12/20

Als u dit jaar zijn vindt dan kunnen deze schuim en het gebruik van de product, plaats de gebruiker contact op te nemen met C. R. Bard, Inc. en te zien of er een van uw nieuwe informatie beschikbaar is.

Bard, **Recovery**, en **Recovery Cone** zijn gedeponeerde handelsmerken van C.R. Bard, Inc. of een van zijn gelieerde bedrijven.

U.S. octrooi nrs 6,007,558 en 6,258,026. Andere octrooien aangevraagd.

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2. Prevention of Pulmonary Embolism. 2009; (Rev. 2). Fleisure 01-0181.

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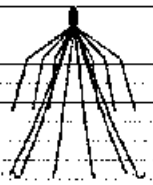
Sistema do filtro Recovery® para utilização na veia cava



PORTUGUÊS

Informação de utilização

Cuidado: A lei Federal (E.U.A.) limita a venda deste dispositivo a um médico ou por ordem de um médico.

A. Informação geral

O filtro *Recovery* representa uma nova geração de dispositivos de interceção venosa concebidos para prevenir embolias pulmonares. A conceção e material únicos do filtro *Recovery* proporcionam uma excelente eficácia de filtragem e permitem a colocação percutânea através de uma bainha introdutora vascular de 7 French com um mínimo de dificuldades no local de entrada. O procedimento de colocação é rápido e simples de efetuar.

O conjunto original foi concebido para a implantação através do seu cateter introdutor de 63 cm, com D.I. de 7 French utilizando uma guia angulada de 0,035 pol. No fim da guia existe uma ampola concebida para empurrar a ponta do filtro e concebeu-se um segmento estirado para segurar e orientar adequadamente as pernas do filtro. Estes componentes fazem o filtro à guia impulsionar à medida que este último empurra o filtro, com a ponta primeiro, em direção à extremidade distal do cateter, posicionado através da veia ilíaca ou inferior. Quando a ponta do filtro se aproxima da ponta do cateter introdutor, a mesma ficará presa e dobrada pelas extremidades radiopacas do cateter introdutor. O cateter introdutor e o conjunto de libertação são então puxados para cima do punho da guia impulsora de modo a essencialmente e libertar o filtro e permitir que o mesmo volte a retomar a sua forma pré-definida. O sistema para centrar permite que o filtro *Recovery* seja colocado com a ponta do filtro centrada e evita que as pernas se cruzem.

O filtro *Recovery* foi concebido para funcionar como um filtro permanente. Quando clinicamente indicado, o filtro *Recovery* pode ser removido até um máximo de 46 dias após implantação através de uma das técnicas fornecidas em Procedimento de Remoção Opcional. Os ganchos ativos do filtro *Recovery* permitem que o filtro permaneça rígido e preso à migração, mas que defenda elasticamente quando o filtro é removido por via percutânea. (ver Procedimento de Remoção Opcional para conhecer as instruções específicas de remoção).

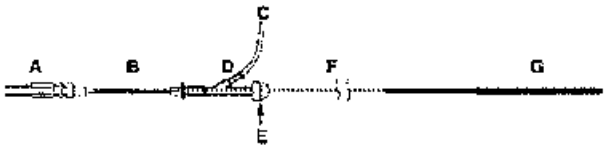
Compatível com RM. O aquecimento do filtro *Recovery* e anexo em RM é não-clínico sem é afetado pelo funcionamento de um aparelho de RM.

B. Descrição do dispositivo

O sistema de filtro *Recovery* consiste num filtro e num conjunto de libertação. O filtro *Recovery* consiste em duas séries de seis fios comerciais em forma de forma que emanam de uma região central de filtro. Estas duas séries formam dois níveis de filtração de ambos as pernas proximais e dois níveis de filtração e de ângulo proximais e num suporte de fixação. O filtro *Recovery* destina-se a ser utilizado em veias cava com diâmetros até 28 mm.

O sistema de libertação do filtro *Recovery* está ilustrado na Figura A. O sistema de libertação consiste numa bainha introdutora com D.I. de 7 French e distal, no filtro *Recovery*, num tubo de armazenamento com adição para perfusão salina e um sistema impulsor. O filtro *Recovery* é instalado pré-instalado no tubo de armazenamento de libertação.

Figura A. Sistema do filtro Recovery



A. CATETER INTRODUTOR
B. TUBO DE ARMAZENAMENTO DO FILTRO
C. CONJUNTO DE PERCUSSÃO SKITA E SLOTA DE SOLUÇÃO SALINA
D. OR FIGIO LATERAL
E. ADAPTADOR TOUHY-BORST AJUSTÁVEL
F. SOLA MPULSORA DE NITINOL
G. PUNHO DA GUIA IMPULSORA

IMPORTANTE: Leia as instruções cuidadosamente antes de utilizar o filtro *Recovery*.

C. Indicações de utilização

O sistema do filtro *Recovery* está indicado para utilização na prevenção de êmbolos pulmonares recorrentes através da colocação permanente na veia cava nas seguintes situações:

- Tromboembolismo pulmonar quando o uso de anticoagulantes é contra-indicado.
- Ausência de terapêutica anticoagulante em doenças tromboembólica.
- Tratamento de emergência após embolia pulmonar maciça quando os benefícios anticoagulantes são superados com a rapidez necessária.
- Embolia pulmonar crónica recorrente quando a terapêutica anticoagulante não é bem sucedida ou é contra-indicada.

O filtro *Recovery* pode ser removido de acordo com as instruções fornecidas no Sección: Procedimento Opcional para a Remoção do Filtro.

D. Contra-indicações de utilização

CUIDADO: Se o diâmetro corrigido da veia cava inferior (VCI) exceder 28 mm, o filtro não deve ser inserido na mesma.

O filtro *Recovery* não deve ser implantado em:

- Doentes grávidas nas quais a radiação pode constituir um perigo para o feto. Os riscos e benefícios devem ser cuidadosamente avaliados.
- Doentes com diâmetros de veia cava superiores a 28 mm.
- Doentes com risco de embolia séptica.

E. Advertências

Implantação do filtro Recovery

1. O filtro *Recovery* para a veia cava e pré-instalado no tubo de armazenamento e destina-se apenas a utilização única. Não coloque o filtro antes de o paciente ser cuidadosamente na veia cava (VCI) já que o filtro *Recovery* não pode ser movido ou reposicionado com segurança no tubo de armazenamento.
2. A libertação do filtro *Recovery* através da bainha introdutora é feita apenas no estado anterógrado. A retração do guia impulsora durante a libertação pode provocar o deslocamento do filtro, o encurtamento das pernas ou dos ganchos do filtro e pode estar que o filtro avance o suficiente na bainha de bainha.
3. O sistema do filtro *Recovery* foi concebido apenas para abordagens femorais. Nunca utilize o filtro *Recovery* e o sistema de libertação para abordagens superiores (veia jugular, subclávia ou antecubital) já que resultará em ventilação inferior o filtro *Recovery* no seu sítio inicial.
4. Se surgir um vendo grande no local de libertação, não tente libertar o filtro através de manobras de perfusão alternativas. É possível prender-se em menos poucos com a guia e com o introdutor.
5. Utilize apenas o Sistema de Remoção *Recovery Cone* para remover o filtro *Recovery*. Nunca tente remover o filtro *Recovery* com qualquer outro dispositivo.
6. Nunca avance a guia ou a bainha introdutora/dilatador sem coloque o filtro sob orientação radioscópica.

Remoção do filtro Recovery

1. Não tente remover o filtro *Recovery* se houver quaisquer quantidades significativas de trombos retidos no filtro ou se a ponta do filtro estiver enterrada na parede da veia cava.
2. Utilize apenas o sistema de Remoção *Recovery Cone* (embalado separadamente) do kind para remover o filtro *Recovery*. A utilização de outros dispositivos resulta em embolias pulmonares recorrentes.

F. Precauções

Implantação do filtro Recovery

1. O filtro deve ser colocado as proximal em mulheres grávidas e em mulheres com estado para perder.
2. As anomalias anatómicas podem complicar a inserção e a colocação do filtro. O cumprimento rigoroso das instruções de Utilização pode diminuir o tempo de inserção e reduzir a probabilidade de ocorrência de dificuldades.
3. Deformações da coluna: É importante ter um cuidado especial quando se planeia a implantação em doentes com deformações osteocondrais significativas da coluna, uma vez que a veia cava inferior pode seguir o trajeto geral destas deformações anatómicas. Esta situação pode exigir a utilização de técnicas avançadas para remover o filtro.

G. Complicações potenciais

- Migração do filtro: Pode ser causado pela colocação em diâmetros de veias cava anteriormente ou que excedem os 28 mm ou no caso de não se utilizarem técnicas de fixação apropriadas.
- Perfuração da parede da veia cava: Pode ocorrer no caso de não se utilizar uma técnica correta de inserção.
- Oclusão caval: Deve considerar-se a probabilidade de ocorrência de oclusão em relação a qualquer caso de recorrência num doente com um êmbolo pulmonar ou que é provável que venha a ter um êmbolo sem a intervenção.

H. Equipamento necessário

É necessário utilizar o seguinte equipamento:

- Um filtro *Recovery* num sistema de libertação que contenha:
  - Um conjunto de bainha introdutora de 45 cm com um D.I. de 7 French e um dilatador.
  - Um tubo de armazenamento com um filtro *Recovery* e sistema impulsor de libertação pré-instalados
  - Guia de 0,035 polegadas com uma ponta em J de 3 mm e um comprimento de 110 cm ou superior
  - Agulha de punção inicial de calibre 18
  - Solução salina
  - Tubo de extensão estéril para o poço a gota ou para perfusão de solução salina
  - Todas as agulhas básicas para venopunção, bisturi lâmina N.º 11, anestesia local, campos cirúrgicos, etc.
  - Kit de punção inicial que consiste de uma guia de 0,035 polegadas com uma ponta em J de 3 mm uma agulha de punção inicial uma lâmina N.º 11 e uma bainha de 10 cm está disponível no C.R. Bard, número do catálogo 400IE

Se o médico escolher remover o filtro *Recovery* por via percutânea, o sistema de remoção *Recovery Cone* está disponível na C.R. Bard, Inc.

I. Instruções de utilização

Inserção de cateter introdutor de 7 French e venografia preliminar

1. Selecione uma via adequada para o acesso venoso femoral, do lado direito ou do lado esquerdo, conforme a tamanho de a anatomia do doente, a preferência do operador ou a localização da trombose venosa.
2. Prepare, coloque os campos cirúrgicos e anestesie o local de punção ao pele de forma normal.
3. Selecione e abra a embalagem do filtro. Abra a embalagem do kit A de acesso inicial.
4. Faça uma incisão na pele com a lâmina N.º 11 e efetue a venopunção com uma agulha de punção inicial de calibre 18.
5. Introduza a guia com ponta em J e empurre-a cuidadosamente para o interior da veia cava distal ou da veia ilíaca.

NOTA: Se surgir resistência durante o procedimento de inserção femoral, retire a guia e verifique a profundidade da veia radiograficamente com uma pequena injeção de meio de contraste. No caso de se verificar a presença de um trombo grande, remova a agulha de venopunção e teste na veia do lado oposto. Pode contornar-se um trombo pequeno com uma guia ou com um introdutor.

6. Retire a agulha de venopunção sobre a guia com ponta em J. Empurre o cateter introdutor de 7 French juntamente com o seu dilatador avançado sobre a guia e para o interior da veia cava distal ou da veia ilíaca.

NOTA: O cateter introdutor possui marcadores radio-opacos para auxiliar a visualização e posicionamento do filtro pré-colocação. Os marcadores radio-opacos no cateter introdutor proporcionam uma localização "alvo" entre a qual o filtro deve ser posicionado imediatamente antes de se desembainhar e de colocar.

7. Remova a guia e o dilatador, deixando o cateter introdutor com a sua ponta na veia cava distal ou na veia ilíaca. Faça uma irrigação manual e de forma intermitente ou agite ao cateter uma perfusão gota a gota contendo de solução salina, para manter a patência do cateter introdutor.

NOTA: O conector do cateter introdutor tem uma concepção interna especial. Deve assegurar-se que as seguintes peças Fêmea, pode ser utilizada uma faca suficiente que possa penetrar totalmente no conector.

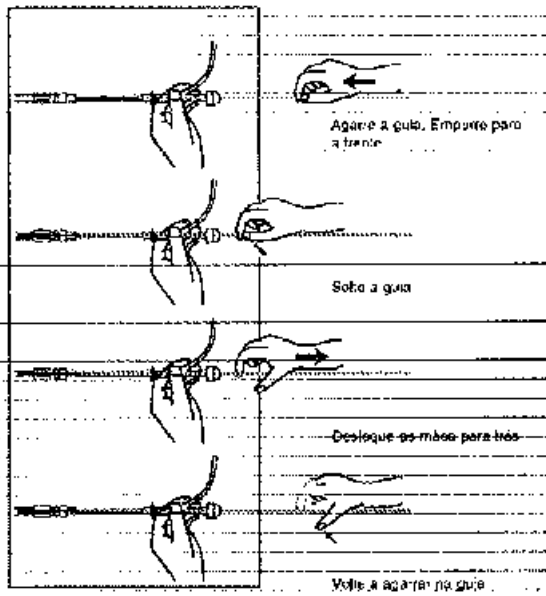
8. Realize um venocavograma inferior padrão normalmente 30 ml do meio de contraste a 15 ml/s) "Verifique se existem trombos na veia cava, quais a posição dos vasos renais e de outras anomalias congénitas. Determine a mais apropriada colocação do filtro e meça o diâmetro da VCI, corrigido em termos de ampliação (normalmente de 20 por cento).

9. Avance o cateter introdutor até ao nível selecionado sob orientação fluoroscópica. A guia e o dilatador devem ser removidos para facilitar este processo. Para a inserção femoral, a ponta do cateter introdutor deve ficar 1 cm abaixo do veio ilíaco mais inferior.
10. Retire o fluxo e o sistema de liberação do Kit B.
11. Ligue um saco de 500 ml de solução salina ao orifício lateral do adaptador em Y, introduza o conjunto de perfusão para a guia posicionada. Deixe a perfusão de solução salina fluir em redor do filtro no tubo de armazenamento durante 5 segundos de modo a arrastar todo o para a ponta pelo através do cateter introdutor. Ajuste o conjunto de perfusão de modo a proporcionar uma taxa lenta de gotejamento. Ajuste a válvula de três vias para minimizar o refluxo de solução salina para o saco de fluxo, e impeça que a guia impulsora avance livremente.

NOTA: É muito importante manter a patência do cateter introdutor com a irrigação da solução salina de modo a que o segmento estilado que segura a cúpula corretamente se possa do filtro não fique com coágulos. Esta situação interferirá com a colocação do filtro.

12. Prenda a extremidade livre do tubo de armazenamento do filtro ao cateter introdutor com fita para manter a via permeável. Isto garante solução salina flua para o interior da VCI quando seguir os passos. O cateter introdutor e o patência de liberação do filtro devem ser mantidos em linha reta para maximizar o atrito.

Ilustração do avanço do filtro.



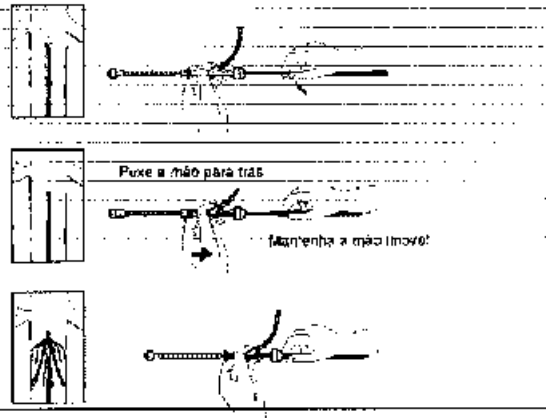
13. Empurre o filtro movendo a guia impulsora do núcleo para a frente através do cateter introdutor, empurrando filtro em cada movimento de avanço da guia impulsora (Figuras B-E). Não puxe a guia impulsora para trás, empurre-a apenas para a frente. Para conveniência do operador, pode-se fazer uma ligação na guia impulsora do núcleo, sem que isso provoque fissuras no material de núcleo, para facilitar o manuseamento e o avanço da guia impulsora.
14. Continue a empurrar a guia impulsora para a frente até o ponto do filtro coincidir com o marcador radio-opaco na extremidade distal do cateter introdutor. Nessa altura, o punho da guia impulsora deve estar adjacente ao adaptador em Y.

Libertação/colocação do filtro

15. Liberte e solte o filtro conforme descrito abaixo:
    Figura F: Segure com firmeza no punho da guia impulsora
    Figura F-1: O filtro encontra-se posicionado no cateter introdutor entre os marcadores radio-opacos antes da colocação na VCI.

NOTA: Não liberte o filtro empurrando-o para além da extremidade do cateter introdutor. Em vez disso, desembainhe o filtro puxando retrações o cateter introdutor conforme descrito abaixo.

Ilustração da libertação do filtro



Agora solte o filtro desembainhando-o na VCI da seguinte modo:

Posicione a ponta do filtro 1 cm abaixo da veia renal mais inferior.

Figura G: Mantenha uma mão imóvel, a outra mão puxe o conjunto do adaptador em Y e tubo de armazenamento para trás completamente sobre o punho, desembainhe e libertando o filtro.

Figura G-1: Desembainhar o filtro na VCI

Figura H: Posição dos fios ao completar o processo de desembainhar.

Figura H-1: Filtro colocado na VCI

16. Agora retire a guia impulsora para o exterior do tubo de armazenamento segurando com firmeza no conjunto fixado pelo adaptador em Y, pela luva de alívio de tensão e pelo cateter de introdução e puxe-os para fora a guia impulsora.
17. Passe com irrigação com a solução salina *aberta* ao cateter para permitir que a gota continua para manter a patência do cateter introdutor.

Cavenograma de seguimento

18. Pode efectuar-se uma flebocavografia de seguimento depois de retirar o cateter introdutor para o enfermeiro da veia ilíaca (normalmente 30 ml de meio de contraste a 15 ml/s).
19. Remova o cateter introdutor e faça uma compressão de rotina sobre o local de punção da bainha inicial para obter a hemostase.

PROCEDIMENTO OPCIONAL PARA REMOÇÃO DO FILTRO:

Remoção do filtro Recovery

CUIDADO: Recomenda-se vivamente que a remoção do filtro Recovery seja feita utilizando apenas o Recovery Cone.

Equipamento necessário

É necessário ter o seguinte equipamento:

- Um sistema de remoção *Recovery Cone* que contem:
  - Um conjunto de bainha de dilatação de 75 cm com 10 French de D.I. e o dilatador
  - Um adaptador em Y com *Recovery Cone* e um sistema impulsor de libertação
- Guia de 0,035 polegadas com uma ponta em J de 3 cm e um comprimento de 110 cm ou superior
- Agente de punção inicial de calibre 18
- Introdutor de 12 French
- Solução salina
- Tubo de extensão estéril para a guia e de solução salina ou uma seringa para perfusão da solução salina
- Todos os materiais básicos para venipunção básica (bainha 6 F 11, arteriotomia local, compressão de

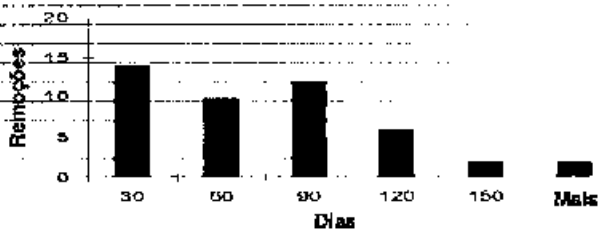
Experiência clínica

O filtro *Recovery* foi utilizado no Canadá por um investigador e dois colaboradores, em seis hospitais da área de Toronto em 58 indivíduos, de acordo com as normas do Acesso Especial.

Embora quase todos os médicos utilizasse o dispositivo, a remoção foi efectuada pelos três médicos, com pessoal de apoio e equipamento radiográfico habituais.

Dos 55 filtros implantados, foi recuperado um total de 45. 8 permaneceram colocados e 4 doentes morreram com os filtros colocados devido a causas não relacionadas com a colocação ou extracção dos filtros (leucemia, cancro, poliomielite e espondilose) motivos (acidente vascular cerebral de hipotensão ortostática). O período de tempo até a remoção do filtro varia entre 1 e 161 dias, com mediana de 60 dias (ver histograma).

Tempo até à remoção



O seguimento após a remoção durou em média 325 dias (intervalo de 1.901 dias). A maior parte dos filtros (n=43) foi extraída através da veia jugular interna direita, mas alguns filtros foram extraídos através da veia jugular interna esquerda (n=1) e da veia femoral (n=1). Um dos filtros não pôde ser recuperado durante uma operação e um cancro, cuja massa estava a afetar o filtro. Os dois métodos descritos nas instruções de utilização foram utilizados para extrair o filtro em todos os casos, com exceção de 4, dos quais se utilizou uma pinça de núcleo em vez de se utilizar o método em vez de se utilizar o sistema de remoção *Recovery Cone*. Contou um caso de embolia pulmonal assintomática quando se obteve a bainha maior.

A única complicação relacionada com a fratura de um braço e garrote na fêmea. Esta fêmea foi colocada por via intra-cervical numa veia grávida durante o terceiro trimestre ao nível de L3-4. Pensa-se que a fratura resultou das forças causadas pelo parto e pela colocação intra-renal, causando uma distensão e avulsão graves do garrote na face lateral das vértebras. O filtro foi retirado sem o garrote.

Quadro sinóptico de superioridade clínica	
Filtros Recovery implantados	58
Remoções percutâneas de filtros	45
Remoções cirúrgicas de filtros	1 (semi-terminal e com resección de um bainha)
Mortes dos pacientes	5 (85 anos (média de 52 anos))
Justificação para a colocação do filtro	
Contra-indicações em relação à anticoagulação	30
Complicações associadas com a anticoagulação	17
Insucesso da anticoagulação	2
Profilaxia	2
Tempo até à remoção	1-161 dias (média de 60 dias)
Seguimento após a remoção	1-901 dias (média de 325 dias)
Complicações resultantes da remoção do filtro	
Tromcos	0
Fractura do garrote resultante das forças causadas pelo	
parto e rasgamento e pela colocação intra-renal	1
Embolia pulmonar assintomática após a remoção	1

Instruções relativas ao procedimento

Inserção do Cateter Introdutor

1. Selecione uma via adequada para o acesso remoto jugular, o lado direito ou o lado esquerdo, dependendo do tamanho ou do anatomia do doente, da preferência do operador ou da localização da trombose oclusa.
2. Prepare, avalie e se possível aborde o local de punção do paciente com o procedimento estéril.
3. Selecione e abra a embalagem de cateter de Recovery Cone. Abra a embalagem do kit do cateter introdutor.
4. Faça uma incisão no pele com a lâmina Nº 11 e dilatar a venopunção com um agulha de punção macia do calibre 18.
5. Introduza o guia e empurre-o com cuidado até ao local onde se encontra o filtro Recovery que pretende remover.
6. Retire a agulha de venopunção sobre a guia.
7. Pré-dilate o vaso ao qual se acoda com um dilatador de 16 French.
8. Remova imediatamente o dilatador de 16 French, puxando-o com a mão direita sobre a guia e para o interior do vaso.

NOTA: O cateter introdutor possui um marcador radiopaco na extremidade distal da bainha do cateter para auxiliar a visualização.

9. Remova a guia e o dilatador, deixando o cateter introdutor com a sua ponta na localização apropriada. Faça uma irrigação manual e de forma intermitente conjugada ao cateter uma perfusão contínua de solução salina, para manter a patência do cateter introdutor.
10. Realize um cavocavograma inferior (pedido imediatamente 30 ml de produto de contraste a 15 ml/s). Verifique se existem trombos no local. Se existirem trombos significativos dentro do filtro, considere a fase Recovery.

Inserção e libertação do Recovery Cone

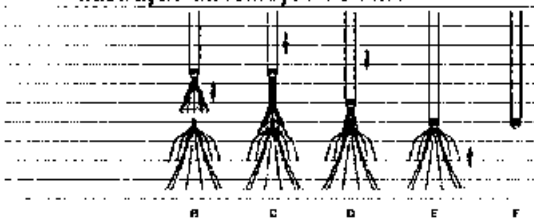
11. Retire o corte e o sistema de libertação do Kit E.
12. Proceda à irrigação do lúmen central do cateter do cone e humedeça o cone com solução salina, de preferência heparinizada.
13. Retraia lentamente o cone para o interior do adaptador em Y para fechar o cone.

NOTA: O cone deve estar totalmente retraído no interior do adaptador em Y antes de fazer o sistema ao cateter introdutor, para se assegurar que o cone pode ser facilmente libertado através do cateter.

14. Ligue um tubo de 500 ml ou uma seringa com solução salina ao orifício lateral do adaptador em Y. Retire a solução salina fluir em todo o cone do adaptador em Y, durante 5 segundos. Aperte a válvula do adaptador Touhy-Borst para impedir o refluxo de solução salina em direcção ao anestesista. Mais nunca de forma a impedir que a haste impulsora avance livremente.
15. Prenda a extremidade macho do adaptador em Y, com o cone fechado, diretamente ao cateter introdutor. O cateter introdutor e o sistema de libertação de filtro devem ser montados em linha reta para minimizar o atrito.
16. Empurre o cone movendo a haste impulsora para a frente através do cateter introdutor, empurrando o cone em cada movimento de avanço da haste impulsora.
17. Continue a empurrar a haste impulsora até o cone avançar o máximo possível para o extremidade distal do cateter introdutor. Desembainhe para abrir o cone aproximando a haste e recolhendo o cateter.

Captura do Filtro Recovery

Ilustração da remoção do filtro



18. A captura do filtro Recovery encontra-se ilustrada nas figuras B-F.

Figura B: Depois do cone ter sido aberto acima do filtro, avance o cone sobre a ponta do filtro mantendo o cateter introdutor estável e empurrando a haste impulsora. Recomenda-se que se obtenha uma imagem radioscópica durante em que pelo menos se o cone está sobre a ponta do filtro.

Figura D: Feche o cone sobre a ponta do filtro empurrando o cateter introdutor sobre o cone ao mesmo tempo que mantém a haste impulsora imóvel.

Figura D: Continue a empurrar o cateter introdutor sobre o cone até este estar dentro do cateter introdutor.

Figura E: Com o cone fechado sobre o filtro, remova o filtro estabilizando o cateter introdutor e retraindo a haste impulsora com um movimento suave e constante.

Figura F: O filtro foi retraído para dentro do cateter.

Remoção do sistema de seguimento

19. Pode obtuar-se um cavocavograma de seguimento após o cateter introdutor (normalmente 30 ml de meio de contraste a 15 ml/s).
20. Remova o cateter introdutor e faça uma compressão de forte pressão no local de punção, da forma normal para obter a hemostase.

Técnica com Auxílio do Guia

Devido a variações anatómicas, nomeadamente a posição do filtro Recovery, podem ser utilizadas técnicas que recorrem ao auxílio de um guia.

Utilização de uma guia

Se for difícil avançar o cone sobre a ponta do filtro Recovery, pode utilizar-se uma guia para facilitar o avanço do cone sobre a ponta do filtro.

Retire a bainha introdutora e a haste do cone para fora da ponta do filtro. Introduza uma guia de 0,035 polegadas através do lúmen central (passe em J ou ponta em ângulo), recomenda-se a utilização de uma guia com revestimento hidrofílico). Empurre a guia através do cone e através do filtro para uma posição proximal da ponta do filtro.

Depois de confirmado que a guia está em contacto ou próximo da ponta do filtro, empurre o cone sobre a guia até abrigo a ponta do filtro.

Empurre a bainha introdutora de modo a fechar ligeiramente o cone sobre a ponta do filtro. Retraia a guia para o interior da haste impulsora.

Continue a remover o filtro conforme descrito ao passo 16.

J. Apresentação

Cada filtro Recovery é fornecido pré-montado no seu tubo de armazenamento. Cada filtro Recovery é estéril e apirogénico, a não ser que a embalagem tenha sido danificada ou aberta, e está pronto a ser utilizado numa única utilização. O tubo de armazenamento e o sistema de libertação não são pré-montados. Se o tubo for acidentalmente esmagado, não o use, pois pode danificar o conteúdo.

Nota: Após utilização, os acessórios e dispositivos de inserção do filtro Recovery podem constituir um risco biológico potencial. Manuseie e elimine-os de acordo com a prática médica e as leis e normas locais, estatais e federais aprovadas.

O filtro Recovery deve ser guardado num local seco (à temperatura ambiente) e fresco.

K. Garantia

A Bard garante ao primeiro comprador deste produto que o mesmo estará isento de defeitos de materiais e de mão-de-obra durante um período de um ano a partir da data do primeiro aplicação. A responsabilidade, ao abrigo desta garantia limitada, será limitada à reparação ou substituição do produto defeituoso, segundo o critério exclusivo da Bard ou ao reembolso do preço pago. O uso e desgaste resultantes da utilização normal ou defeitos resultantes da utilização incorreta deste produto não estão abrangidos por esta garantia limitada.

NA MEDIDA DO PERMITIDO PELA LEGISLAÇÃO APLICÁVEL, ESTA GARANTIA É INVOCADA DO PRODUTO SUBSTITUI TODAS AS OUTRAS GARANTIAS, EXPLÍCITAS OU IMPLÍCITAS, INCLUINDO, MAS NÃO LIMITADA, QUALQUER GARANTIA IMPLÍCITA DE COMERCIALIZAÇÃO OU ADEQUAÇÃO A UM DETERMINADO FIM. EM CIRCUNSTÂNCIA ALGUMA A BARD SERÁ RESPONSÁVEL PERANTE SI POR QUAISQUER DANOS INCIDENTAIS OU INDIRECTOS RESULTANTES DO SEU MANUSEAMENTO OU UTILIZAÇÃO DESTE PRODUTO.

Alguns países não permitem uma exclusão das garantias implícitas de danos acidentais ou indiretos. Pode ter direito a recursos suplementares ao abrigo da legislação do seu país.

Data de emissão da rotulagem: 12/09

Se existir alguma alteração à sua condição de saúde após a implantação deste produto, o utilizador deverá contactar a C. R. Bard, Inc. para verificar se existem informações adicionais sobre este produto.

Bard, Recovery, e Recovery Cone são marcas registadas da C.R. Bard, Inc. ou de uma empresa afiliada.

Patente americana Nº 5,007,552 e 5,258,020. Outras patentes pendentes.

Bibliografia:

1. ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2000 (Rev.12, Effective 01/01/11)

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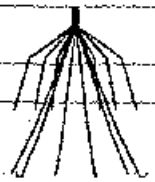
Recovery® Filter System for use in the Vena Cava



ΕΛΛΗΝΙΚΑ

Πληροφορίες Χρήσης

ΠΡΟΣΟΧΗ: Η Ομοσπονδιακή νομοθεσία των ΗΠΑ περιορίζει την πώληση της συσκευής αυτής μόνο σε ιατρό ή κατόπιν εντολής ιατρού.

Α. Γενικές Πληροφορίες

Το Φίλτρο Recovery κατασκευάζεται από ένα γερό ανοξείδωτο φίλτρο διακοπής που έχουν σχεδιαστεί ώστε να αποτρέπουν την πνευμονική εμβολή. Ο μοναδικός σχεδιασμός και το υλικό κατασκευής του Φίλτρου Recovery παρέχουν εξαιρετικό αποτελεσματικό, ξεκάθαρη και σταθερή τοποθέτηση διάρκειας έως τεσσάρων (4) εβδομάδων μετά την εμφύτευση. Η επιβίωση τοποθέτησης, είναι γρήγορη και εύκολη στην εφαρμογή.

Το Κιτ περιλαμβάνει όλα τα απαραίτητα εξαρτήματα για την εισαγωγή του φίλτρου με τη χρήση της τεχνικής Seldinger. Το κιτ περιλαμβάνει ένα εισαγωγέα μεγέθους 9 French, με τη βοήθεια ενός οδηγού σύρματος μήκους 80 cm και εσωτερικής διαμέτρου 0.46 cm (0.035 ίντσες) με ευθύ ή καμπύλο άκρο. Ένα εξάβαλβο σύστημα εισαγωγής έχει σχεδιαστεί ειδικά για να επιτρέπει την ανάκτηση του φίλτρου, ενώ το πλαστικό περίβλημα αυλωτικά τμήμα επιτρέπει τη τοποθέτηση αυτού του φίλτρου. Με την χρήση αυτή το φίλτρο αναρτάται από το άνω μέρος του, με το άκρο μπροστά, προς το περιφερικό άκρο του καθετήρα, κάτω από την κατώτερη κοίλη φλέβα. Όταν το άκρο του φίλτρου προσεγγίσει το άκρο του καθετήρα αναρτήσεως, θα βλέπετε μερικά επαναλαμβανόμενα σημάδια του καθετήρα εισαγωγέα. Στη συνέχεια, ο καθετήρας αναρτήσεως με τη μέγιστη ενισχυμένη ελαστικότητα στον άξονα του συρματος οδήγησης έχει να απασυρθεί το φίλτρο και το φίλτρο να αναπτύξει. Ελέγχετε να εκτιμήσετε το προκαθορισμένο σημείο. Το σύστημα μικροφάσματος επιτρέπει στο Φίλτρο Recovery να επιμηκύνει το άκρο του εγγυημένου και επιτρέπει τη διατήρηση των αγκύλων.

Το Φίλτρο Recovery έχει σχεδιαστεί ώστε να δρατώς μικρό φίλτρο. Οποιαδήποτε κίνηση το Φίλτρο Recovery μπορεί να αποκριθεί διαδρομή έξω από την εμφύτευση του σώματος με τις οδηγίες του κατασκευαστή στην ενότητα Προφυλάξεις Επιμέρους Απόσυρσης. Το ιδανικό φίλτρο του Φίλτρου Recovery είναι σχεδιασμένο φίλτρο να παραμείνει σταθερό και να αποφεύγεται στη μεγαλύτερη, αλλά στην περιοχή διάρκειας επεμβάσεων προκαλών ελαστική παραμόρφωση (Γι α ανωτέρω οδηγίες απόσυρσης βλέπε Προφυλάξεις Επιμέρους Απόσυρσης).

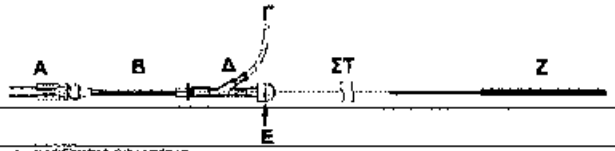
Συμφωνεί με τις διαστάσεις VIR! Το εφυτεύσιμο Φίλτρο Recovery είναι κατασκευασμένο από τις διαστάσεις MRI και δεν παρουσιάζουν ουσιαστικά επιπτώσεις στο πεδίο ακτινογραφίας της συσκευής διέγερσης MRI

Β. Περιγραφή της Συσκευής

Το Σύστημα Φίλτρου Recovery αποτελείται από το φίλτρο και το Σύστημα Απελευθέρωσης. Το φίλτρο Recovery αποτελείται από δώδεκα σκέλη από νήμα κραδασμών ανοξείδωτου χάλυβα σύρματος με κεντρικό άξονα από νήμα. Τα δώδεκα σκέλη σχηματίζουν δύο επίπεδα ζεύξης αγκύλων: το κεντρικό επίπεδο ανάρτησης παρέχεται από τα σκέλη, ενώ το κατώτερο επίπεδο ανάρτησης παρέχεται από τους βραχίονες. Το Φίλτρο Recovery προορίζεται για χρήση σε κοίλες φλέβες διαμέτρου έως 28 mm.

Το Σύστημα Φίλτρου Recovery αποτελείται από: 1 σε 1 το Σύστημα Απελευθέρωσης αποτελείται από έναν καθετήρα αναρτήσεως με Ε.Δ. 7 French με διαταλιό, από το φίλτρο Recovery, έναν σωλήνα φλυαρίας με βύσμα έγχυσης τρού, και ένα σύστημα ωθητήρα. Το φίλτρο Recovery συσκευάζεται προ τοποθετημένο εντός του σωλήνα φλυαρίας.

Εικόνα Α. Σύστημα Φίλτρου Recovery



Α ΚΑΘΕΤΗΡΑΣ ΕΙΣΑΓΩΓΕΑΣ
Β ΣΥΣΤΗΜΑΣ ΦΥΛΑΚΗΣ ΚΕΝΤΡΟΥ
Γ ΕΞΩΤΕΡΙΚΗΝ ΕΠΙΦΑΝΕΙΑ ΘΗΚΗΣ
Δ ΠΛΕΥΡΙΚΗ ΘΥΡΑ
Ε ΡΥΘΜΙΣΤΗΣ ΠΡΟΣΑΡΜΟΓΕΑΣ ΤΟΥΗΥ-BORST
ΣΤ ΕΥΡΙΝΑ ΟΔΗΓΗΣΗ ΑΠΟ ΝΙΤΙΝΟΛ
Ζ ΑΥΛΟΣ ΤΟΥ ΣΥΡΜΑΤΟΣ ΟΔΗΓΗΣΗ

ΣΗΜΕΙΩΣΗ: Μην χρησιμοποιήσετε το Φίλτρο Recovery εφόσον τα οδηγία τροποποιηθεί.

Γ. Ενδείξεις Χρήσης

Το Σύστημα Φίλτρου Recovery προορίζεται για την πρόληψη της υποτροπιάζουσας πνευμονικής εμβολής δια μέσης τοποθέτησης στην κοίλη φλέβα της φλεβικής αγγειακής.

- Παγιωμένες θρομβοεμβολή εάν η χορήγηση αντιπηκτικών αντενδείκνυται.
- Απουσία επαρκούς σκληρής ανάταση ή άλλη δραματοποίηση νόσου.
- Επιβαρυνόμενη ιατρική ιστορικό ανεπαρκή εμβολή όπως τα αναφερόμενα αρχεία της ταχύτητας σταλής ή/και μεγάλης.

Χρήση, αντιπρόσωπος ή ιατρικό ή εμβολή επειδή η ανάπτυξη ή αφαίρεση δεν έχει αποδειχθεί ότι αντενδείκνυται.

Το φίλτρο Recovery μπορεί να αφαιρεθεί εάν μετά τα οδηγία του παρόντος στη Ενότητα: Προφυλάξεις Επιμέρους Αποσύρσης (Φίλτρα.)

Δ. Αντενδείξεις Χρήσης

ΠΡΟΣΟΧΗ: Αν η διορθωμένη διάμετρος της κάτω κοίλης φλέβας (ΚΚΦ) υπερβαίνει τα 28 mm, το φίλτρο δεν θα πρέπει να εισαχθεί στην ΚΚΦ.

Το Φίλτρο Recovery δεν θα πρέπει να εφαρμόζεται σε:

- Ενεργός λοίμωξη επειδή η φλεβοκομπική ενέργεια να αίσθηση το τμήμα. Οι λοιμώξεις θα πρέπει να θεραπεύονται πριν τα συσκευή προκειται ή
- Ασθενής με διάμετρο κοίλης φλέβας πάνω από 28 mm.
- Ασθενείς που δεν είναι κατάλληλοι αγγείων

Ε. Προειδοποιήσεις

Εμφύτευση του Φίλτρου Recovery

1. Το φίλτρο κοίλης φλέβας Recovery είναι προορισμένο μόνο για μονήρη συνήθης μη προορίζεται για μόνιμη χρήση. Τοποθετήστε σύμφωνα το φίλτρο στην κοίλη φλέβα (ΚΚΦ) πριν από οποιαδήποτε άλλη. Φίλτρο Recovery αν υπάρχει να επανατοποθετηθεί ή με σταθερά στον σωλήνα φλυαρίας.
2. Η επανατοποθέτηση του Φίλτρου Recovery έχει μόνο δοκιμαστεί σε θρομβική μεταβολή μόνο μία φορά. Τυχόν επέκταση του συστήματος καθήκει κατά την αποτυχημένη θρομβοεμβολή με αφαίρεση με αφαίρεση του Φίλτρου Recovery συνιστάται η αφαίρεση με βραχύτερο σε μεσαία και αφαίρεση αφαίρεσης του Φίλτρου Recovery.
3. Το Σύστημα Φίλτρου Recovery έχει σχεδιαστεί ώστε να τοποθετηθεί μόνο μέσω της τεχνικής Seldinger. Προσέξτε για να τοποθετήσετε το Φίλτρο Recovery με το Σύστημα Απελευθέρωσης Recovery σε το Σύστημα Απελευθέρωσης για τροφοδοσία από φλέβα που βρίσκεται σε μεγάλο βαθμό από το φίλτρο τροχοπέδη, ανεπαρκή, βεβαιωθείτε, διότι αν είναι δυνατόν να τοποθετήσετε το σύστημα πριν επιστρέψετε στο Φίλτρο Recovery πριν, τοποθετήσετε φλέβας.
4. Αν παρουσιαστεί μεγάλης δύσκολης στο άρμα επιλέγοντας σύμφωνα επαναπροώθησης, μην επιχειρήσετε να απελευθερώσετε το φίλτρο δίχως σύμφ. Επιχειρήστε την αποκατάσταση του φίλτρου από αναλογικά σε μια Αν ο δρόμος αντιμετωπίζει με τον ιατρό από το υδρό σύρμα και τον ιατρικό.
5. Αποφύγετε το Φίλτρο Recovery μόνο με το Σύστημα Απελευθέρωσης Recovery Cone. Πριν μη αποσύρετε το κάθε φίλτρο το στερεό έχει στοιχεία.
6. Πριν μην προσθέτε τα σύρματα ή τις διαπλεύσεις για συγκεκριμένα μεγάλα μεγέθη, τα μέσα όρια, ή βραχιονική καθετήρας.

Απόσυρση του Φίλτρου Recovery

1. Μην επιχειρήσετε να αποσύρετε το φίλτρο Recovery αν υπάρχει σημαντική ποσότητα θρόμβου παγιωμένη μέσα στο φίλτρο ή αν το άκρο του φίλτρου έχει ενσωματωθεί στο τοίχωμα της κοίλης φλέβας.
2. Για να αναπτύξετε το Φίλτρο Recovery χρησιμοποιήστε συγκεκριμένα το Σύστημ Απελευθέρωσης Recovery Cone της Bard. Η χρήση άλλων συσκευών έχει προ αλλεργικό υποτροπιάζοντα πνευμονική εμβολή

ΣΤ. Προειδοποίηση

Εμφύτευση του Φίλτρου Recovery

1. Εάς έγκαιρα γίνεται ως στις φλέβες που βρίσκονται σε ηλικία τοποθέτησης, το φίλτρο θα τρέπει να τοποθετείται ύπαρξη του εσπερδών των νεφρικών.
2. Τυχόν ανωμαλίες κάψερρους τοίχους να περιλάβουν την εισαγωγή και την εκπνοή του φίλτρου. Η προσεκτική ανάπτυση αυτών των Οδηγών Χρήσης μπορεί να μειώσει το χρόνο επέμβασης και την πιθανότητα ως ανωμαλίες διάσεως.
3. Διαμόρφωση της Γενικότητας Στέλης. Οι ασθενείς με σημαντικές ενδοκοιλιακές διαμορφές της αποκλίσεις στέλη είναι σημαντικό να εξετάζονται με προσοχή, διότι ο κάτω κοίλη φλέβα ενδέχεται να σκαλώσει τη νοσηλεία των σταθερών διαστρεβλώσεων. Στην περίπτωση αυτή, η διαστρεβλωμένη απόσυρση του φίλτρου ενδέχεται να είναι δύσκολη.

Απόσυρση του Φίλτρου Recovery

1. Τυχόν σημαντικές διαφορές πάνω να περιπλέξουν τη διάσπαση ασφαλούς με ύπαρξη του Συστήματος Απόσυρσης Recovery Cone. Η προσεκτική ανάπτυση αυτών των Οδηγών Χρήσης μπορεί να μειώσει το χρόνο επέμβασης και την πιθανότητα ως ανωμαλίες διάσεως.
2. Συνιστάται της Γενικότητας Στέλης. Οι κεντρικοί τροποποιημένοι υποστηρικτικοί του φίλτρου Recovery με το Σύστημα Απόσυρσης Recovery Cone σε ασθενείς με σημαντικές ενδοκοιλιακές διαμορφές της αποκλίσεις στέλη είναι σημαντικό να εξετάζονται με προσοχή, διότι ο κάτω κοίλη φλέβα ενδέχεται να σκαλώσει τη νοσηλεία των σταθερών διαστρεβλώσεων. Στην περίπτωση αυτή, ενδέχεται να αποφεύγεται η τροποποίηση του φίλτρου.

Ζ. Πιθανές Επιπλοκές

- Δεν προσεκτική και σύμφωνη. Κατά μικρού το σφάλμα σε ασκούμενη ή ανεπαρκείς κοίλη φλέβα διάμετρο. φλεβικό βάθος ή στη μη χρησιμοποιημένη κατάλληλης ιατρικής σφάλματος.
- Διάτρηση του τοιχώματος της κοίλης φλέβας. Κατά μικρού να σφάλμα σε δεν χρησιμοποιείται κατάλληλη τεχνική εισαγωγής
- Αποκλεισμός της κοίλης φλέβας. Το ενδεχόμενο δικό θα πρέπει να αναπτύσσεται με βάση το ιατρικό ιστορικό ή/και τα παρακολούθηση σε δεν υπάρχει παγίωση
- Δεν προσεκτική και σύμφωνη. Κατά μικρού το σφάλμα σε ασκούμενη ή ανεπαρκείς κοίλη φλέβα διάμετρο. φλεβικό βάθος ή στη μη χρησιμοποιημένη κατάλληλης ιατρικής σφάλματος.
- Διάτρηση του τοιχώματος της κοίλης φλέβας. Κατά μικρού να σφάλμα σε δεν χρησιμοποιείται κατάλληλη τεχνική εισαγωγής
- Αποκλεισμός της κοίλης φλέβας. Το ενδεχόμενο δικό θα πρέπει να αναπτύσσεται με βάση το ιατρικό ιστορικό ή/και τα παρακολούθηση σε δεν υπάρχει παγίωση
- Δεν προσεκτική και σύμφωνη. Κατά μικρού το σφάλμα σε ασκούμενη ή ανεπαρκείς κοίλη φλέβα διάμετρο. φλεβικό βάθος ή στη μη χρησιμοποιημένη κατάλληλης ιατρικής σφάλματος.
- Διάτρηση του τοιχώματος της κοίλης φλέβας. Κατά μικρού να σφάλμα σε δεν χρησιμοποιείται κατάλληλη τεχνική εισαγωγής
- Αποκλεισμός της κοίλης φλέβας. Το ενδεχόμενο δικό θα πρέπει να αναπτύσσεται με βάση το ιατρικό ιστορικό ή/και τα παρακολούθηση σε δεν υπάρχει παγίωση

Η. Απαιτούμενος Εξοπλισμός

Ο ακόλουθος εξοπλισμός είναι απαραίτητος για τη χρήση.

Ένα Φίλτρο Recovery το ένα Σύστημα Απελευθέρωσης όπου τα περιέχουν:

- Ένας θήκης εισαγωγέα με μήκος 45 cm και Ε.Δ. 7 French με σχισμούζα
- Ένας σωλήνας φλυαρίας με προτοποθετημένο Φίλτρο Recovery και ένα σύστημα επανεκκίνησης καθετήρα
- Οδηγός Σύρμα 0.035 ιντσών με άκρο σχήματος "J" 3 mm, μήκους 180 cm ή μεγαλύτερο
- Βελόνα εισόδου 18 gauge
- Ψαλίδι
- Σύριγγα προσέτσης για σπέρνει ροή ή έγχυση ιρού
- Ένα το βασικό υλικό για φλεβοκομπική σκόπι. Λιπάδα αρ. 11, κατσή ενσωμάτωσης, πρόσ, κτ.
- Η C. R. Bard διαθέτει τα εξαρτήματα αποκλειστικά στο ένα οδηγό σύρμα 0.035 ιντσών με άκρο σχήματος "J" 3 cm. Δεν ενσωμάτωση, σχήμ. αρ. 15 και σύριγγα των 10cc (αρχ. απαίτηση: 4C10E)

Λιπάδα ιατρικός σκόπι θα να αποσυρθεί διάμετρο το Φίλτρο Recovery το Σύστημα Απελευθέρωσης Recovery Cone διαθέτει και από την C. R. Bard, Inc.

Θ. Οδηγίες Χρήσης

Εκτοπισμός του Καθετήρα Εισαγωγέα 7 French και Προετοιμασία Φλεβογραφία

1. Επιλέξτε μία κατάλληλη μεγάλη φλέβα από πρόσβασης, είτε στη δεξιά είτε στην αριστερή μηρική, ανάλογα με τις διαστάσεις ή την ανατομία του ασθενούς, την προτίμηση του χειριστή ή το σημείο της φλέβας θρόμβωσης.
2. Προετοιμάστε, καθαρίστε και αναισθητοποιήστε το σημείο παρακέντησης της επιλεγμένης κατά τον καθιερωμένο τρόπο.
3. Επιτύχετε και ανοίξτε τη συσκευασία του φίλτρου. Αναζητήστε τη Κιτ Χρήσης συσκευασίας του Καθετήρα Εισαγωγέα.
4. Χορηγήστε την επιδερμίδα με μία λεπίδα αρ. 11 και κάνετε φλεβοκομπική με μία βελόνα εισόδου 18 gauge.
5. Εισαγάγετε το οδηγό σύρμα άκρου σχήματος "J" και προωθήστε το προσεκτικά στην άνω κοίλη φλέβα ή στη δεξιάς φλέβας.

ΣΗΜΕΙΩΣΗ: Αν κατά την επιτυχή μηχανής εισαγωγής συναντήσετε αντίσταση, αποσύρετε το οδηγό σύρμα και ελέγξτε τη βελόνα φλεβοκομπική με μικρή έγχυση σκιαγραφικού. Αν παρουσιαστεί μεγάλος θρόμβος, αποσύρετε τη βελόνα φλεβοκομπική και προσπαθήστε να εισάγετε από τη φλέβα της αντίθετης πλευράς. Αν ο θρόμβος είναι μικρός, μπορεί να παρακαμφθεί από το οδηγό σύρμα και τον καθετήρα.

6. Αφαιρέστε τη βελόνα φλεβοκομπική, πάνω από το οδηγό σύρμα αφού σχήματος "J". Προωθήστε τον σύρμα εισαγωγέα 7 French μαζί με τον καθετήρα διαστολέα πάνω από το οδηγό σύρμα, στην άνω κοίλη φλέβα ή στη δεξιάς φλέβας.

ΣΗΜΕΙΩΣΗ: Ακολουθήστε προσεκτικά διαδέτει ακτινοσκοπικές σημάνσεις για να αποφύγετε τη σωστή απόσυρση καλύτερα τοποθέτηση του φίλτρου πριν από την εκτύπωση. Οι ακτινοσκοπικές σημάνσεις είναι που κάνει να προσέχετε ορισμένων με περιοχή - "σώμα", όπου θα πρέπει να βρίσκεται το φίλτρο. πριν από την αφαίρεση του δακτυλίου καλύτερα.

7. Αποφύγετε το οδηγό σύρμα και τον καθετήρα αφαίρεσης το άκρο του καθετήρα εισαγωγέα στην επιφάνεια κοίλης φλέβας ή στη κοίλη φλέβα. Περάστε ή αφαίρεση με τον καθετήρα με το χέρι ή προσεκτικά του σύρμα οδηγού σύρμα έγκαιρα προσέχτε το ακτινοσκοπικό δάκτυλο.

ΣΗΜΕΙΩΣΗ: Ο ομφαλός του καθετήρα με συγκρατητικό διαθέτει ειδικό σχεδιασμό. Θα πρέπει να δίδεται προσοχή ώστε οι συνδέσεις να σφίγγονται καλά, αλλά όχι με πολύ δύναμη, διότι θα μπορούσε να προκληθεί θραύση του ομφαλού.

8. Εκτελέστε αρχική φλεβογραφία της κάτω κοίλης φλέβας (ενδεικτικά εγχεόμενα 30 ml σκιαγραφικού μέσου σε 15 ml/s). Ελέγξτε για τυχόν θρόμβους μέσα στη φλέβα, τη θέση των νεφρικών φλεβών και για τυχόν συγγενείς ανωμαλίες. Επιλέξτε το βέλτιστο επίπεδο για την τοποθέτηση του φίλτρου και μετρήστε τη διάμετρο της ΚΚΦ, διορθώνοντας τη μεγέθυνση (μέγιστο 28 mm) [illegible]

9. [illegible] ο καθετήρας [illegible] Δεν [illegible] να [illegible] το άκρο του καθετήρα [illegible] 1 cm [illegible] φλέβα.

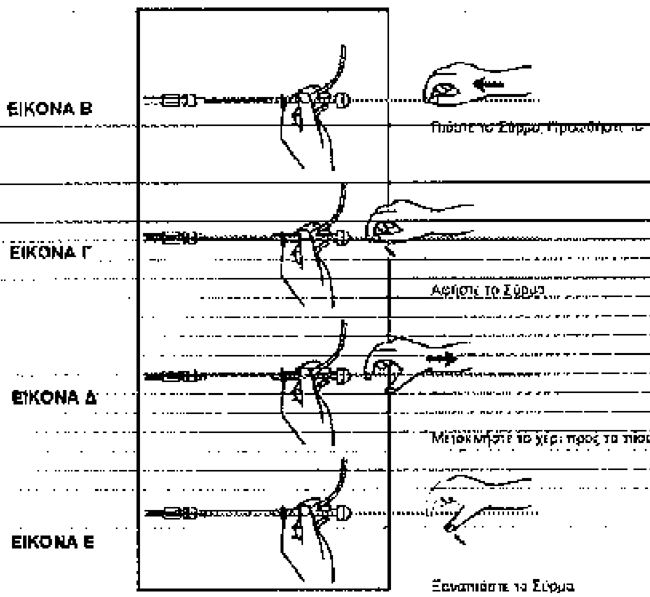
10. Αφαιρέστε το φίλτρο και το σύστημα απελευθέρωσης από τη θήκη [illegible]

11. Συνδέστε έναν σάκο ορού 500 ml [illegible] του προσαρμογέα σχήματος Y [illegible] φλέβα [illegible] ώστε να [illegible] του καθετήρα [illegible] να επιτρέψει γρήγορη ροή [illegible] Touhy-Borst [illegible] του ορού [illegible] του καθετήρα.

ΣΗΜΕΙΩΣΗ: Η διατήρηση του καθετήρα [illegible] είναι πολύ σημαντικό να διατηρείται με τη διοχέτευση του ορού, έτσι ώστε το [illegible] που στηρίζει και προστατεύει [illegible] το φίλτρο να μην αποφραχθεί. Κάτι τέτοιο θα εμπόδιζε την εκτίναξη του φίλτρου.

12. Προσαρτήστε τη [illegible] φίλτρου [illegible] καθετήρα [illegible] στη φλέβα [illegible] του εγχεόμενου ορού στην ΚΚΦ. Ο καθετήρας [illegible] σύστημα απελευθέρωσης του φίλτρου θα πρέπει να διατηρηθεί [illegible]

Προώθηση του Φίλτρου, Εικονογραφημένη



13. Προωθήστε το Φίλτρο [illegible] το σύρμα ωθητήρα [illegible] προς τα εμπρός. [illegible] του καθετήρα [illegible] με κάθε κίνηση του σύρματος του ωθητήρα προς τα εμπρός, προωθείται και το φίλτρο (Εικόνες Β-Ε). Μην τραβάτε προς τα πίσω το σύρμα ωθητήρα [illegible] το σύρμα ωθητήρα [illegible] βρόχο [illegible] με την προώθηση του σύρματος ωθητήρα.

14. Συνεχίστε την προώθηση του σύρματος του ωθητήρα [illegible] το άκρο του φίλτρου [illegible] του καθετήρα [illegible] του σύρματος [illegible] προσαρμογέα σχήματος Y.

Απελευθέρωση/Έκπτυξη του Φίλτρου

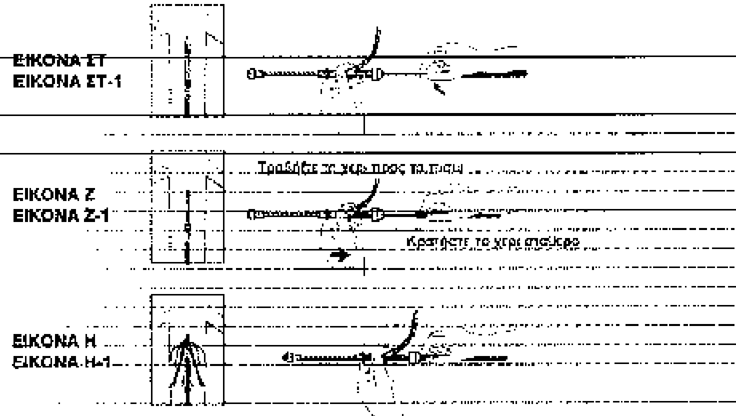
15. Απελευθερώστε το φίλτρο όπως περιγράφεται στη συνέχεια.

Εικόνα ΣΤ: Κρατήστε σταθερό τη λαβή του σύρματος ωθητήρα

Εικόνα ΣΤ-1: Φίλτρο τοποθετημένο στον καθετήρα [illegible] πριν από την έκπτυξη στην ΚΚΦ.

ΣΗΜΕΙΩΣΗ: Μην προωθήσετε το φίλτρο [illegible] το άκρο του καθετήρα [illegible] Αντιθέτως, [illegible] το φίλτρο [illegible], αποσύροντας τον καθετήρα [illegible] όπως περιγράφεται στη συνέχεια.

Απελευθέρωση του Φίλτρου, Εικονογραφημένη



Στη συνέχεια, απελευθερώστε το Φίλτρο στην ΚΚΦ [illegible] ως εξής:

Τοποθετήστε το άκρο του Φίλτρου 1 cm κάτω από την κατώτερη νεφρική φλέβα.

Εικόνα Ζ: Κρατώντας το με το ένα χέρι σταθερό, τραβήξτε τη διάταξη του σωλήνα φύλαξης και τον προσαρμογέα σχήματος Y προς τα πίσω, ευθέως πάνω από τη λαβή, ώστε να αποκαλυφθεί και να απελευθερωθεί το φίλτρο.

Εικόνα Ζ-1: Αγκίστρι [illegible] από το Φίλτρο εντός της ΚΚΦ

Εικόνα Η: Η θέση των χεριών [illegible] της διάταξης [illegible]

Εικόνα Η-1: Το Φίλτρο εκπτυγμένο εντός της ΚΚΦ

16. Τώρα αποσύρετε το σύρμα ωθητήρα προς τα πίσω, εντός του σωλήνα φύλαξης, κρατώντας [illegible] προσαρμογέα σχήματος Y, [illegible] φύλαξης και τον καθετήρα απελευθέρωσης [illegible] το σύρμα ωθητήρα προς τα πίσω.

17. [illegible] να [illegible] καθετήρα [illegible]

Αγγειογράφηση Παρακολούθησης της Κοίλης Φλέβας

18. [illegible] την απόσυρση του καθετήρα [illegible] παρακολούθησης της κοίλης φλέβας (ενδεικτικά εγχεόμενα 30 ml σκιαγραφικού μέσου στα 15 ml/s).

19. [illegible] τον καθετήρα [illegible] πίεση στο σημείο της παρακέντησης [illegible] επίτευξη αιμόστασης.

ΠΡΟΑΙΡΕΤΙΚΗ ΕΠΕΜΒΑΣΗ ΓΙΑ ΤΗΝ ΑΠΟΣΥΡΣΗ ΤΟΥ ΦΙΛΤΡΟΥ:

Απόσυρση του Φίλτρου Recovery

ΠΡΟΣΟΧΗ: Η απόσυρση του Φίλτρου Recovery συνιστάται ιδιαιτέρως να πραγματοποιείται αποκλειστικά με το Recovery Cone.

Απαιτούμενος Εξοπλισμός

Ο ακόλουθος εξοπλισμός είναι απαραίτητος για τη χρήση:

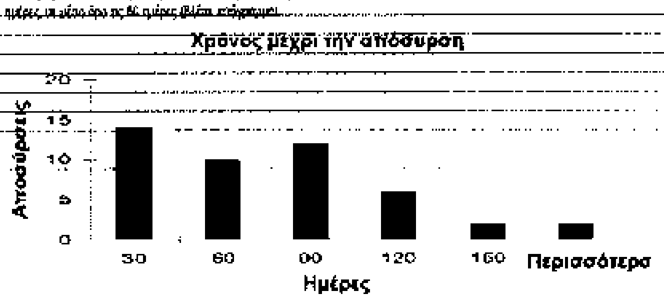
- Ένα Σύστημα Απόσυρσης Recovery Cone που περιέχει:
  - Ένα θηκάρι απελευθέρωσης με μήκος 75 cm και Ε.Δ. 10 French και ένα διαστολέα
  - Έναν προσαρμογέα σχήματος Y με Κώνο Ανάκτησης (Recovery Cone) και ένα σύστημα απελευθέρωσης καθετήρα
- Οδηγό Σύρμα 0,035 ιντσών με άκρο σχήματος "J" 3 mm, μήκους 110 cm ή μεγαλύτερο
- Βελόνα εισόδου 18 gauge
- Διαστολέας των 12 French
- Ορός
- Σετ [illegible] για [illegible] ορού
- [illegible]

Κλινική Εμπειρία

Το Φίλτρο Recovery έχει χρησιμοποιηθεί στον Καναδά [illegible] σε 58 [illegible] σύμφωνα με τους κανονισμούς περί Ειδικής Πρόσβασης (Special Access)

[illegible] από έναν γιατρό [illegible] από τους γιατρούς που [illegible]

Από τα 58 [illegible] φίλτρα, [illegible] 45,2 [illegible] 4 [illegible] φίλτρα [illegible] Ο χρόνος μέχρι την απόσυρση [illegible] 1 και 161 ημέρες [illegible] 60 ημέρες [illegible]



Η παρακολούθηση μετά την απόσυρση [illegible] 325 ημέρες (εύρος 1-801 ημέρες). Τα [illegible] φίλτρα (n=40) [illegible] (n=1) [illegible] (n=1). [illegible]

η μοναδική άλλη οδηγία ενόψει με που αναφέρεται ηταν η έρευνα ενός βραζιλιάνου κατόικου θησαυρών. Το εν λόγω άρθρο σας πληροφορεί ότι κατά το εστιτόδε των ναρκών σε έρευνα γενικά του βραζιλιάνου ήρθηκε της ενημερώσης της, στο σπιτάκι των ιατρικών επισκόπων [...2], η βρύση στο σώμα στην πλάση του αρχείου λόγω του κινητού και λόγω του σημείου τοποθέτησης κάνει από τα στήθη του ναρκών, με όχι ως συνέπεια την τοποθέτηση του φίλτρου και τη διάσωση του στο οποίο από τις επανειλημμένες στήριξη. Το φίλτρο αποκλείστηκε χωρίς το άνοιγμα

Συνοπτικός Πίνακας Κλινικής Εμπειρίας	
Συμπτωματικά Φίλτρα Ηπατικών	56
Διαθέσιμες Διαστάσεις Φίλτρων	45
Χρησιμοποιήσεις Απομάκρυνσης Θρόμβων	3 (παρατηρήθηκε με την εκτεταμένη εμπειρία)
Μέγιστο Χρόνος	8-89 ετών (μέσος όρος: 52 ετών)
Λόγοι τοποθέτησης του Φίλτρου	
Αντικανονική αντιπηκτικής δράσης	40
Επαναλαμβανόμενες με την αντιπηκτική δράση	13
Αναπηρίας αντιπηκτική δράση	3
Λόγοι τοποθέτησης	2
Χρόνος μέχρι την επάνοδο	1-165 ημέρες (μέσος όρος 61 ημέρες)
Διάστημα παρακολούθησης μετά την απόσυρση	1-901 ημέρες (μέσος όρος 325 ημέρες)
Επιπλοκές Απόσυρσης Φίλτρου	
Τρυπάνι	0
Θρόμβωση και έμφραγμα λόγω της πλάκας ή συσσώρευση, κατά τον χρόνο της λήψης τοποθέτησης κατωτερού τμήματος του καναλιού	1
Ασυμπτωματική τοποθέτηση εμβολή μέσα από την απόσυρση	1

Οδηγίες Τοποθέτησης

Εισαγωγή του Καθετήρα Εισαγωγής

1. Εκτελέστε μία οπτικοποίηση χαμηλού τύπου προσέγγισης στη δεξιά σας ή αριστερή πλευρά, ανάλογα με τις διαστάσεις ή την σύνθεση του ασθενούς την βραδιάση του χειρισμό ή το σημείο της ή λήψης βρόχων ης.
2. Προσαρμόστε, εκλύστε και ανακαθαρίστε το κομμάτι τοποθέτησης της επιφάνειας, όπως τον τοποθετημένο φρόνο.
3. Επιλέξτε και ανοίξτε τη συσκευασία του καθετήρα **Recovery Cone**. Ανοίξτε το Κιτ Α της συσκευασίας του Καθετήρα Εισαγωγής.
4. Χαρίζει τον επιθετικό με το λιπαντικό ης. 11 ως ελάχιστα ενεβεπαρουσιαστικό με με βελόνα εκούδου 18 gauge.
5. Εισαγάγετε το οδηγό σύρμα και προωθήστε το προς τον στη βένη του άγκιστρο το φίλτρο **Recovery** που προστατεύει στόχους.
6. Αφαιρέστε τη βελόνη ελεγχόμενης τομής πολύ από το οδηγό σύρμα.
7. Προβάτε σε προσαρμογή του προσπελάσιμου αγγείου με τον διαστολέα των 12 French.
8. Προωθήστε τον καθετήρα εισαγωγής 12 French μαζί με τον πυρήνα του διαστολέα πολλαπλά το οδηγό σύρμα και μέσα στη φλέβα.

ΣΗΜΕΙΩΣΗ: Ο καθετήρας εισαγωγής διαθέτει αντικειμενική σημανση στο περιφερικό άκρο του θαλάμου του καθετήρα για τη διευκόλυνση της απεικόνισης.

9. Αφαιρέστε το οδηγό σύρμα και τον διαστολέα, αφήνοντας τον καθετήρα εισαγωγής με το άκρο του στην κατάλληλη θέση. Πριν από προβάτε σε έκπλυση του καθετήρα με το χέρι ή προσέχτε τον συνεχή σπάγγο έγχυση χρησιμοποιώντας το ένεσμα ή βαλτωτό του.
10. Επιλέξτε κατάλληλο σημείο της κάθε κοίλης φλέβας (κάτω χαμηλότερα 30 mL απεικόνιση σε 15 mL). Ελέγξτε για θρόμβους μέσα στο φίλτρο. Αν μέσα στο Φίλτρο έχει παρόντα σημαντικές ποσότητα θρόμβου, μη απομακρύνετε το Φίλτρο **Recovery**.

Εισαγωγή και Χειρισμός του Recovery Cone

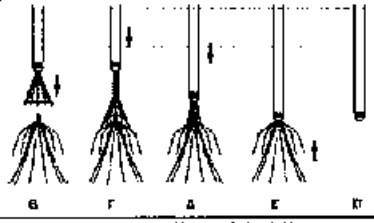
11. Αποσύρετε τον κώνο και τα σύστημα υποστήριξη από το Κιτ Β.
12. Ρυθμίζει τη λειτουργία του κινητικού εμπόδιο του κώνου και εφαρμόστε τον με αρό – κατά προσέγγιση με γαντζωτό αρό.
13. Αποσύρετε αρό του κώνου μέσα στον τροποποιημένο σφιγκτήρα Y έτσι ώστε να καταρρέει ο κώνος.

ΣΗΜΕΙΩΣΗ: Ο κώνος πρέπει να έχει αποσυρθεί πλήρως εντός του προσαρμοσμένου σφιγκτήρα Y πριν από τη σύνδεση του συστήματος στον καθετήρα εισαγωγής, έτσι ώστε να εξασφαλίζεται η σωστή διέλευση του κώνου διαμέσου του καθετήρα.

14. Συνδέστε έναν σάκο αρού 500 mL ή μια συριγγα με σάλ στην πλευρική σχισμή Y. Επιτρέψτε τη ροή του υγρού για να γεμίσει ο σωλήνας από την άκρη απόσυρσης στον προσαρμοσμένο σφιγκτήρα Y για τουλάχιστον 5 λεπτά. Σφίξτε το βαλβίδα του προσαρμογέα Tuohy-Borst κάτω από τον άξονα του καθετήρα εισαγωγής, έτσι ώστε να σταματά η ροή του αρού προς τα σημεία εισαγωγής, αλλά όχι τόσο σφιχτά ώστε να εμποδίζει η ολίσθηση προς τον τερματισμό του καθετήρα.
15. Προσαρτήστε το σφιγκτό άκρο του προσαρμοσμένου σφιγκτήρα Y με τον κώνο που έχει τοποθετηθεί στο εσωτερικό του καθετήρα εισαγωγής. Ο καθετήρας εισαγωγής και το σύστημα απελευθέρωσης του φίλτρου θα πρέπει να διατηρούνται σε κάθετη θέση για την ολοκλήρωση της λύσης.
16. Προωθήστε τον κώνο μεταπώλησης του άξονα του καθετήρα προς το εμπρός, διέξοδο του καθετήρα εισαγωγής από μια κλίση του άξονα του καθετήρα προς τα κάτω προκειμένου κατά τον κώνο.
17. Συνεχίστε την προώθηση του άξονα του καθετήρα έως ότου ο κώνος φύσει στην αντίσταση σημείο στο οποίο ο καθετήρας εισαγωγής βγάλει τα δάκρυα για να ανοίξει τον Κώνο, διαμορφώνοντας τον άξονα και επιτρέποντας τον καθετήρα.

Σύλληψη του Φίλτρου Recovery

Απόσυρση του Φίλτρου, Εικονογραφημένη



18 Η σύλληψη του Φίλτρου Recovery παρουσιάζεται στις Εικόνες Β-1 Τ

Εικόνα Β: Αρχική κλίση εμπλοκής του φίλτρου, προωθήστε τον καθετήρα εισαγωγής προς τα κάτω για να προσδώσετε την κλίση του άξονα του καθετήρα. Συνεχίστε να βεβαιώνεστε ότι ο άξονας βρίσκεται πάνω από το άκρο του Φίλτρου για να αποφύγετε ενδεχόμενη βλάβη του φίλτρου.

Εικόνα Γ: Κλείστε τον κώνο πίσω από το άκρο του Φίλτρου, προωθώντας τον καθετήρα εισαγωγής από τον Κώνο και κρατώντας παράλληλα τον Φίλτρο στο καθετήρα εισαγωγής.

Εικόνα Δ: Συνεχίστε να αφαιρείτε τον καθετήρα εισαγωγής πίσω από τον κώνο, έως ότου ο κώνος βρίσκεται στο εσωτερικό του καθετήρα εισαγωγής.

Εικόνα Ε: Μόλις ο κώνος έχει τοποθετηθεί πλήρως από το άξονα, σταθεροποιήστε το Φίλτρο σταθεροποιώντας τον άξονα του καθετήρα εισαγωγής και αποσύροντας τον Κώνο και τον άξονα του καθετήρα με μία αργή, σταθερή κίνηση.

Εικόνα ΣΤ: Το Φίλτρο έχει απομακρυνθεί πλήρως από τον καθετήρα

Αντιμετώπιση Παρεπιπτώσεων της Κοίλης Φλέβας

19 Εάν κατά την απόσυρση του καθετήρα εισαγωγής βρεθεί τα άκρα του Φίλτρου στο εσωτερικό του καθετήρα εισαγωγής, αποσύρετε τον καθετήρα εισαγωγής και το Φίλτρο ταυτόχρονα ως μονάδα.

20 Αναζητήστε τον καθετήρα εισαγωγής και το Φίλτρο για θρόμβο πριν από την αφαίρεση της, παρατηρώντας κατά τη διάρκεια της απόσυρσης, αν υπάρχει.

Οδηγίες Χειρισμού - Τροποποιημένη Τεχνική

Λόγω ανατομικών περιορισμών σε ασθενείς με θέση του Φίλτρου **Recovery**, μπορεί να χρειαστεί μια τροποποιημένη οδηγία σύρματος.

Χρήση Οδηγού Σύρματος

Αν δυσκολεύεστε να προωθήσετε τον κώνο πέρα από το άκρο του Φίλτρου **Recovery**, μπορεί να χρησιμοποιηθεί το οδηγό σύρμα κατά τη διάρκεια αυτής.

Αποσύρετε το θηκάρι εξαγωγής και τον άξονα του κώνου μεταξύ από το άκρο του Φίλτρου. Εισαγάγετε ένα οδηγό σύρμα 0.035 inch διάμετρο του κέντρου φλέβες (με άκρο σχήμα μπαστούνι 3 cm) κατά άκρο. Συνεχίστε η χρήση οδηγού σύρματος μέχρι επιλογής. Προωθήστε το οδηγό σύρμα διάμεσο του κώνου και του Φίλτρου, έτσι ώστε το άκρο του Φίλτρου.

Αφού βεβαιωθείτε ότι το οδηγό σύρμα έχετε εισαγάγει βαθιά μέσα στο άκρο του Φίλτρου, προωθήστε τον κώνο πάνω από το οδηγό σύρμα από άκρο του Φίλτρου.

Προωθήστε το θηκάρι εισαγωγής έκκεντρο να καταρρίψει η υπερίδα του κώνου από το άκρο του Φίλτρου. Αποσύρετε το οδηγό σύρμα μαζί με τον κώνο του καθετήρα.

Συνεχίστε την απόσυρση του Φίλτρου όπως περιγράφεται στα βήματα 16.

Πώς παρέχεται

Κιτ Φίλτρο **Recovery** παρέχεται προ αποστειρωμένο στο σύστημα φύλλης του Κιτ Φίλτρο **Recovery** ένα σύρμα κατά τη διάρκεια εφόσον η συσκευασία του δεν έχει ανοιχτεί ή υποστεί ζημιά και εντός έτους ης ημερομηνίας. Ο σωλήνας φύλλης για το σύστημα απελευθέρωσης είναι προαιρετικό. Αν τα φίλτρο είδλε ακουσίως μην επιχειρήσετε να το επαναποστειρώσετε ή να το επαναποθετήσετε.

Σημείωση: Μετά τη χρήση, τα συσκευή σφράγισμα του κιτ **Recovery** να τοποθετηθούν σε σακούλα βιοαπορριμμάτων. Ο χειρισμός και η πιθανή τους χρήση να γίνεται σύμφωνα με την ακόλουθη ιατρική πρακτική και τους ισχύοντες τοπικούς κανονισμούς και οργανωσιακούς βιοαπορριμμάτων κανονισμούς.

Το Φίλτρο **Recovery** θα πρέπει να χρησιμοποιείται με προσοχή περιορισμένο διαστήματος χρήσης.

Κ. Εγγύηση

Η Bard εγγυάται στην αρχική αγοραστή του προϊόντος αυτού ότι το προϊόν είναι απαλλαγμένο ελαττωμάτων, όσον αφορά το υλικό και την κατασκευή, για περίοδο ενός έτους από την ημερομηνία της πρώτης αγοράς. Η εγγύηση περιορίζεται στην επιστροφή ή αντικατάσταση του ελαττωματικού προϊόντος κατά την αποκλειστική κρίση της Bard, η οποία μπορεί, πριν πιστωθεί. Η παρούσα εγγύηση δεν καλύπτει: τερματικούς σφιγκτήρες λόγω ρευστοποίησης κρίσης ή επιπλοκές που οφείλονται σε λανθασμένη χρήση του προϊόντος αυτού.

ΠΛΗΝ ΜΕΤΡΑ ΠΟΥ ΕΠΙΤΡΕΠΕΤΑΙ ΑΠΟ ΤΗΝ ΙΣΧΥΟΥΣΑ ΝΟΜΟΘΕΣΙΑ, Η ΠΑΡΟΥΣΙΑΣΘΕΝΗ ΑΥΤΗ ΕΓΓΥΗΣΗ ΥΠΟΚΑΘΙΣΤΑ ΚΑΘΕ ΑΛΛΗ ΕΓΓΥΗΣΗ, ΡΗΤΗ Η ΣΙΩΠΗΡΗ, ΣΥΜΠΕΡΑΛΑΜΒΑΝΟΜΕΝΗ, ΑΛΛΑ ΧΩΡΙΣ ΝΑ ΠΕΡΙΟΡΙΖΕΤΑΙ ΚΑΜΙΑ ΣΕ ΑΥΤΗ, ΚΑΙ ΚΑΘΕ ΕΜΜΕΣΗΣ ΕΓΓΥΗΣΗ ΕΜΠΟΡΕΥΣΙΜΟΤΗΤΑΣ Η ΚΑΤΑΛΛΗΛΟΤΗΤΑΣ ΓΙΑ ΜΙΑ ΣΥΓΚΕΚΡΙΜΕΝΗ ΣΚΟΠΟ. Η BARD ΔΕΝ ΑΝΑΛΑΜΒΑΝΕΙ ΟΥΔΕΜΙΑ ΕΥΘΥΝΗ ΓΙΑ ΤΥΧΑΙΕΣ Η ΠΑΡΕΠΟΜΕΝΕΣ ΖΗΜΙΕΣ ΠΟΥ ΠΡΟΚΥΠΤΟΥΝ ΑΠΟ ΤΟ ΧΕΙΡΙΣΜΟ Η ΤΗ ΧΡΗΣΗ ΤΗΣ ΠΡΟΪΟΝΤΟΣ ΑΠΟ ΟΠΟΙΟΔΗΠΟΤΕ ΣΑΣ.

Σε καμμία περίσταση δεν ευθύνεται η εξέταση των έμμεσων εγγυήσεων καθώς και των τυχόν ή παρεπόμενων ζημιών. Εάν δυνατόν νομίμως περιορίζεται όλες τις εγγυήσεις με τη γενικότητα της χώρας πολιτείας σας.

Ημερομηνία Έκδοσης Επικαιρότητας: Δεκέμβριος 2008

Σε περίπτωση που έχουν περάσει πάνω από ένα χρόνο από την ημερομηνία αυτή και το χρόνο χρήσης του προϊόντος, η εταιρεία θα πρέπει να επικοινωνήσει με την C. R. Bard για να διασφαλίσει ότι πρόκειται για πλήρως επικαιροποιημένες πληροφορίες σχετικά με το προϊόν.

Bard, Recovery, και Recovery Cone είναι σήματα κατατεθέντα της C. R. Bard Inc. ή συγγενικές της εταιρείες σε ανταγωνισμό στις Η.Π.Α. και/ή άλλες αναγνωρισμένες διεθνείς συμβάσεις.

Βιβλιογραφία:

1. ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2000 (Res. 12), Effective 01/01/01

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Bard Limited
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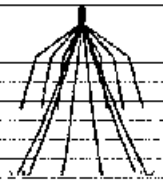
Recovery® Filter-system til brug i vena cava



DANSK

Brugerinformationer

Forsigtig: I henhold til amerikansk lov (USA) må denne anordning kun sælges af eller ordineres af en læge.

A. Generelle informationer

Recovery Filteret består af en rustfri metaltråd med specielle egenskaber, som er udviklet til at forebygge komplikationer. Recovery Filterets unikke design og materiale giver en gennemsnitlig fiksationskraft og tillader perkutan placering med et minimum af skridt på patientens vej til et korrekt angiografisk/fluoroskopisk udført med en indvendig diameter på 7 Fr. Placeringsproceduren er hurtig og enkel at udføre.

Det fremgår af en beregnet hældning gennem et 48 cm langt cylindrisk dilatationsrør med en indvendig diameter på 7 Fr. og en tilsvarende rumfangsgrænse på 3 ml. Den proksimale ende af tråden er beregnet til at skulle på filterets hvile, og det segment, der er beregnet til at holde filterets ben og vende den rigtigt. Disse dele fastholder filteret til kernekomponenten, mens det kun filteret fra med spidsen forevist. Til den distale ende af filteret, der er placeret under den nederste renale vene. Når filterets spids nærmer sig spidsen af indføringsrøret, vil den blive placeret mellem de røntgentætte markører på indføringsrørets ende. Indføringsrøret og indføringsspidsen markerer derpas længde på fluoroskopiske gros for at få filteret ud af røntgenet og frigivet, således at det kan genvinde sin oprindelige form. Centrerings-systemet gør det muligt at holde Recovery Filteret ud, så filterspidsen er centreret, og hvis det er ønskeligt.

Recovery Filteret er beregnet til at fungere som permanent filter. Hvis der er klinisk indikeret, kan Recovery Filteret udtages perkutant efter implantation i henhold til den vejledning, der er givet under Særskilt Udtagningsprocedure. Recovery Filterets kvalitative langsigtede effekt, og hvorvidt migration, mm. deformeres diagnostisk, bør filteret fjernes perkutant.

(Se Særskilt Udtagningsprocedure for specifik anbefalingsvejledning).

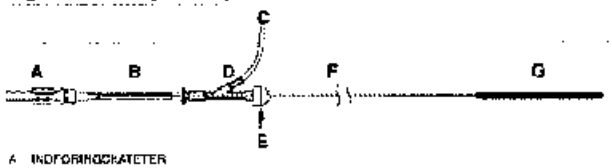
Miljøoplysninger: Recovery Filter-implantat er MR-sikkert ved in vitro-prøver eller prøves at fungere at en MR-enhed.

B. Beskrivelse af anordningen

Recovery Filter-systemet består af filter og indføringssystem. Recovery Filteret består af tolv rustfrie metaltråde med formål at minimere de skader, der kan opstå på en centralt nervesystem. Disse tråde danner to niveauer til tilvejebringelse af emboli. Benene udgør det laveste niveau, og armene det øverste tilvejebringelsesniveau. Recovery Filteret er beregnet til brug i vena cava med diameter på op til 28 mm.

Recovery Filter-indføringssystemet er illustreret på figur A. Indføringssystemet består af et indføringsrør og dilatator med en ydre diameter på 7 Fr. Recovery Filteret, et opbevaringsrør med en indvendig diameter på 7 Fr. og et fremføringssystem. Recovery Filteret er placeret i det distale indføringsrør.

Figur A. Recovery Filter-system



A INDFØRINGSKATETER
B INTRODUCERINGSRØR
C SALTVANDSDRYPINFUSIONSSÆT
D SIDEPORT
E JUSTERBAR TOUHY-BORST-ADAPTER
F NITINOL FREMFØRINGSTRÅD
G GREB TIL FREMFØRINGSTRÅD

VÆRTIGT: Gennemlæs hele vejledningen, før Recovery Filteret tages i brug.

C. Indikationer for brug

Recovery Filter-systemet er beregnet til brug ved forebyggelse af lungeembolisk sygdom via permanent placering i vena cava i følgende situationer:

Pulmonal tromboembolisk, hvor antikoagulation er kontraindiceret.

Svigtende antikoagulationsbehandling for tromboembolisk sygdom.

Kombination af begge ovenstående.

Kardiopulmonal reservebegrænsning, hvor en forventede for dette ved konventionel behandling af begrænset.

Kronisk, tilbagevendende lungeemboli, hvor antikoagulationsbehandlingen har svigtet eller er kontraindiceret.

Recovery Filter kan udtages efter de instruktioner, der angives nedenstående under særskilt procedure for filterudtagning.

D. Kontraindikationer for brug

FORSIGTIG: Hvis den korrigerede diameter for vena cava (IVC) overstiger 28 mm, må filteret ikke indsættes i IVC.

Recovery Filteret må ikke implanteres hos:

Gravide patienter, da fostervækst kan bringe fosteret i fare. For dette og følgende bør nøje overvejes.

Patienter med en vena cava diameter på over 28 mm.

Patienter med risiko for septisk emboli.

E. Advarsler

Recovery Filter-implantation

1. Recovery Filteret, vena cava-filter er beregnet udelukkende i opbevaringsrøret og er kun beregnet til engangsbrug. Filteret må ikke bøjes ud, før det placeres korrekt i vena cava (IVC), da Recovery Filteret ikke med sikkerhed kan tages tilbage i opbevaringsrøret.
2. Placering af Recovery Filteret gennem indføringskateteret kan kun skal kræve gennemlysning. Fluoroskopering af indføringsrøret, dilatationsrør, indføringsrør og markører, der kan ses under gennemlysning, skal kontrolleres i vigtige fremføring af filteret.
3. Recovery Filter-systemet er kun beregnet til fremføring ved hjælp af Recovery Filter og indføringssystem til superior adgang (enten jugulær, subclavia eller antecubital), da dette vil medføre, at Recovery Filteret kommer til at vende forkert i vena cava.
4. Hvis der påvises store thromber på den oprindelige placering, skal man ikke forsøge at placere filteret på den måde, da lille thrombe kan passeres med guidewiren og indføreren.
5. Brug kun Recovery Cone Removal System til udtagning af Recovery Filteret. En udtaget filter må aldrig placeres igen.
6. Fejl ved fjernelse af filteret kan medføre alvorlige komplikationer. Fjern aldrig Recovery Filteret uden fluoroskopisk kontrol.

Udtagning af Recovery Filteret

7. Forsøg ikke at fjerne Recovery Filteret, hvis der er tilstrækkelig bevægelse mellem filterets ben og indføringsrøret, eller hvis indføringsrøret er indført i vena cava-væg.
8. Brug kun Bard Recovery Cone Removal System (patron, separat) til udtagning af Recovery Filteret. Anvendelse af andre anordninger kan resultere i tilbageværende fragmenter.

F. Forsigtighedsforanstaltninger

Implantering af Recovery Filteret

1. Filteret skal placeres i superiorvenøst position hos gravide kvinder og børn kræver særlig opmærksomhed.
2. Anatomiske forhold gør det komplicerede indføring og placering af filteret. Hvis denne vejledning ikke følges, kan indføringsbesværlig, og anordningsfejl for problemer reduceres.
3. Spiralse deformationer: Det er vigtigt at udvise forsigtighed, når man overvejer at indføre et Recovery Filter med Recovery Cone Removal System hos patienter med signifikante kyfotiske/skoliotiske spinaldeformationer. Hos vena cava-filtre kan følge sådanne anatomiske deformationer gøre det svært. Dette kan kræve yderligere teknikker for at fjerne filteret.

Udtagning af Recovery Filteret

1. Anatomiske forhold gør den komplicerede indføring og placering af Recovery Cone Removal System. Hvis denne vejledning ikke følges, kan indføringsbesværlig, og anordningsfejl for problemer reduceres.
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G. Potentielle komplikationer

Migration af filteret. Dette kan forekomme, hvis der ikke anvendes korrekt indføringsteknik.

Perforation af vena cava-væggen. Dette kan forekomme, hvis der ikke anvendes korrekt indføringsteknik.

Occlusion af vena cava. Sandsynligheder for at denne forekommer, skal opvejes med det medfølgende forhold mellem risikofaktorer for en patient, der er udsat for en lungeembolie, eller som sandsynligvis vil opleve dette, hvis der ikke gøres det.

H. Nødvendigt udstyr

Følgende udstyr er nødvendigt for anvendelsen:

- Et Recovery Filter og indføringssystem, som medfølger.
- En 48 cm lang indføringskateter med 7 Fr. ydre- og indvendig.
- En opbevaringsrør med indfør Recovery Filter og indføringssystem.
- 0,038" 3 mm guidewire med J-spids, 110 cm eller længere.
- 18 gauge nål for ingang ind i vene.
- Saks, evt.
- Steril indføringsskål til saltvandsdrypinfusion, præg af sterilt indføringsrør.
- Røntgenkontrast materiale til vena cavografi. Skalpelmesser, lokalbedøvelse, anbefalingsmidler etc.
- En indføringsrør bestående af en 0,038" 3 mm guidewire med J-spids, indføringsnål m. Tilslutning og 10-cc sprøjte fås fra C. R. Bard, katalognummer 400C.

Kun lægen vælger at udtage Recovery Filteret perkutant fra Recovery Cone Removal System fra C.R. Bard, Inc.

I. Brugsanvisning

Indføring af det 7 Fr. indføringskateter og placering af filter:

1. Vælg en egnet femoral adgangsvej, vælg højre eller venstre side, afhængigt af patientens anatomi eller tidligere procedurer eller placeringen af venøse bypasser.
2. Klargør, afdæk og anæstesér hudområdet til standard.
3. Vælg og åbn filterpakningen. Åben kun A indføringskateterpakningen.
4. Foretag et snit i huden med et nr. 11 blad og foretag venepunktur med en 18 gauge indføringsnål.
5. Indfør guidewiren med J-spids og før den forsigtigt ind i den dybe vena cava eller vena iliaca.

BEMÆRK: Hvis der opstår problemer under en femoral indføringsprocedure, trækkes guidewiren tilbage, og venen kontrolleres fluoroskopisk med en lille injektion af kontrastmedium. Hvis der påvises en stor thrombe, fjernes venepunkturstedet, og der forsøges med venen i modsat side. En lille thrombe kan passeres med guidewiren og indføreren.

6. Fjern venepunkturstedet over guidewiren med J-spids. Før det 7 Fr. indføringskateter sammen med den korte dilatator ind over guidewiren og ind i den dybe vena cava eller vena iliaca.

BEMÆRK: Indføringskateteret har røntgentætte markører som hjælp ved visualisering og forud-placering af filteret. De røntgentætte markeringer på indføringskateteret udgør en "target"-placering. Imellemrummet mellem disse skal placeres, når kateteret fjernes, og filteret udfoldes.

7. Fjern guidewiren og stiletten og aftestet indføringskateteret med spidsen i den dybe vena cava eller vena iliaca. Skyl med heparinopløsning eller saltvand. Saltvandsinfusion til kateteret for at bevare indføringskateterets åbning.

BEMÆRK: Indføringskateteret er midtenstykke har en special indvendig opbygning. Sørg for at forskjøv samlinger fast, men uden unødig kraftanvendelse, som kan medføre brud på midtenstykket.

8. Foretag et standard vena cava inferior venogram (typisk 30 ml kontrastmedie med 15 ml/sek.). Check for thromber i vena cava, placeringen af renale vener og medfødte anomalier. Vælg det optimale niveau for filterplacering og mål IVC diameteren ved det korrigeres for forstørrelse (typisk 20 procent).
9. Fjern indføringskateteret, hvorved det valgte niveau under fluoroskopisk kontrol. Guiden ret og dilatatoren bør genindføres for at lette dette. Ved femoral indføring skal kateterspidsen være 1 cm under den nederste renale vene.
10. Fjern filteret og indføringssystemet fra Kit B.
11. Tilslut en 50 ml pose med saltvand til sideporten på Y-adapteren med et stemmen mellem-massel. Lad saltvandsstrømmen løbe omkring filteret i opbevaringsrøret i 5 sekunder for at blødgøre det for passage gennem indføringskateteret. Justér indføringsventilen for at give en lille indføringshastighed. Tilspænd Touhy-Borst adapterventilen for at min mere tilstrækkelig af saltvand, men lak det ikke så meget, at indføringsrøret ikke kan fjernes fra hinanden.

BEMÆRK: Det er meget vigtigt at fjerne indføringskateterets tilslutning med saltvandsinfusionsrør, så det fleksible segment, der holder filterbenene og sørger for, at de vender rigtigt, ikke fjernes med dette. Dette vil gribe ind i filterplacering.

12 Fastgør den fri ende af filteropsamlingsrøret direkte til indføringsskaftet, som allerede ligger i venen, så silhuetten kan observeres på fluoroskopskærmen. Indføringsskaftet og indføringssystemet skal holdes på et lige stykke for at minimere friktionen.

Filterfremføring, illustreret

FIGUR B

Grib fat om tråden. Skub den frem ad

FIGUR C

Slip tråden

FIGUR D

Flyt håndens bagpart

FIGUR E

Tag fat om tråden igen

13 Fremfør filteret ved at bevæge stålstramningsrørets fremadrettede bevægelse gennem indføringsskaftet, så filteret lettes fremfører med hver fremadrettede stålstramningsbevægelse (figur B-E), indtil den sidste stålstramningsrør, den må kun skubbes fremad. For at gøre det lettere for operatøren at måle filterets fremføringsafstand kan stålstramningsrøret markeres op, uden at det kommer i kontakt med filteret, så det bliver nemmere at håndtere og fremføre indføringsrøret.

14 Fortsæt fremføringsbevægelsen med indføringsrøret, indtil fluoroskopien viser, at den fri ende af filteret er placeret i den ønskede position. Fjern derefter indføringsrøret og stålstramningsrøret. Placeringsmarkøren på indføringssystemets greb ligger ved siden af Y-adapteren.

Filterfrigørelse/placering

15 Indsæt og frigør filteret som beskrevet nedenfor.

Figur F: Hold fast i indføringsskaftets greb.

Figur F-1: Filtrets positionsmarkører i indføringsskaftet mellem de røntgentætte markører for placering i IVC

BEMÆRK: Placer ikke filteret ved at skubbe det fjerneste af indføringsskaftet. Træk i stedet hele det stationære filter ved at trække indføringsskaftet tilbage som beskrevet nedenfor.

Filterfrigørelse, illustreret

FIGUR F
FIGUR F-1

FIGUR G
FIGUR G-1

Træk håndtaget tilbage

Hold håndtaget stationært

FIGUR H
FIGUR H-1

Frigør og filteret ved at trække håndtaget til det IVC som følger.

Placér filteropsamleren i en vinkel på ca. 45 grader i forhold til den nedadgående venøse vene.

Figur G: Hold den ene hånd stationært og brug den anden til at trække Y-adapteren og opbevaringsrøret helt tilbage over gribet, så filteret udløses og frigøres.

Figur G-1: Frigørelse af filteret i IVC

Figur H: Håndernes placering ved afslutningen af afslutningsprocessen

Figur H-1: Filteret placeret i IVC.

16 Træk nu indføringsskaftet helt ud af opbevaringsrøret ved at holde fast i Y-adapter, opbevaringsrør og indføringsskaftet og trække indføringsskaftet tilbage

17 Benyttes den intermittende suveredesprøjte eller venstre angiokateter for at bevare indføringsskaftets åbning

Optagende Venøsavgram

18 Det kan ønskes at optagende venøsavgram efter, at indføringsskaftet er trukket tilbage i vena cava inferior (typisk 30 ml kontrastvæske med 15 ml/sek.)

19 Fjern indføringsskaftet og anlæg kompression over punktureringsstedet på halsvenen for at opnå hæmostase

SÆRSKILT PROCEDURE FOR FILTERUDTAGNING:

Udtagning af Recovery Filteret

FORSIGTIG: Det anbefales stærkt, at udtagning af Recovery Filteret kun foretages med Recovery Cone.

Nødvendigt udstyr

Følgende udstyr er nødvendigt for anvendelsen

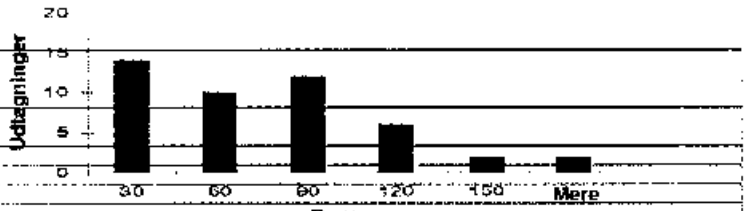
- 1 Recovery Cone Removal System-pakkesæt
- En 75 cm lang indføringsskede med 11 F indvendig og udvendig mål
- En Y-adapter med Recovery Cone og placeringsmarkørsæt
- 0,035" 3 mm guidewire med J-spids, 150 cm lang eller længere
- 18 gauge nålepunkteringssæt
- 12 Fr. dilatator
- Saks
- Stift for længere tid at bibeholde placering af sterile instrumenter
- Den grundlæggende anvendelse af fluoroskopi. Skolet medarbejder, så både fluoroskopist, angiografisygeplejerske og klinisk erfaring

Recovery Filteret er blevet anvendt i Canada til at forhindre og behandle patienter med lungeembolisme i venøse områder på 58 forsøgspersoner under betingelserne for Study-udgang.

Selv om det i høvesagen kun var en læge, der anvendte anordningen, med udtagning som formålet at læge med tilstrækkelig klinisk erfaring og træningsbaggrund.

Ud af de 58 implanterede filtre er i alt 40 udtaget. 5 er blevet sidekende, og 4 patienter er døde med indsat filter af årsager, som ikke havde nogen relation til filterobservering eller udtagning (leukæmi, cancer, polytrauma og pulmonal aspergillose og forskellige slagtilfælde). Tid til udtagning strækker sig fra 1 til 161 dage, gennemsnitlig 60 dage (se histogram).

Tid til udtagning



Optagning efter udtagning har gennemsnitlig tegnet på 325 dage, (afsluttende dag fra 1–904 dage. De første (n=40) blev udtaget via den høje vena jugularis interna (n=1) og de sidste 4 vene (n=4). En blev udtaget kirurgisk under en cancer-operation, hvor en stor vaskulær ramponde på filteret. De to metoder, der er beskrevet i Brugervejledningen, blev anvendt til udtagelse af de resterende 35 filtre, hvor der blev anvendt en større slæde, idet der ofte blev anvendt en større slæde for at anvende Recovery Cone-fjernelse System. Der var ni tilfælde af asymptomatisk pulmonal emboli ved anvendelse af den større slæde.

Den største rapporterede perforering var 0,1 mm. Filteret blev placeret intravaskulært hos en gravid kvinde (uden for studiet) i gennemsnit på perioden 1,1-4,2. Fraktionen mentes at være en følge af bøjningen på grund af indføring og indføring gennemsnit, indtil medicinsk afslutning af studien og udtagning af fugen blev overvejet nødvendig. Filteret blev udtaget uden tegn.

Oversigtstabel over Klinisk erfaring	
Recovery Filtre implanteret	58
Perkutane filterudtagninger	45
Kirurgiske filterudtagninger	1 (Samtidig med tumorresektion)
Patientens alder	8–69 år (62 år gennemsnit)
Årsag til filterindsættelse	
Kontraindikation for antikoagulation	40
Komplikationer i forbindelse med antikoagulation	13
Antikoagulationssvigt	3
Profylakse	2
Tid til udtagning	1–161 dage (60 dage gennemsnit)
Opfølgning efter udtagning	1–904 dage (325 gennemsnit)
Filterudtagningskomplikationer	
Tårebrist	0
Hæmatom som følge af balloninflation med vene og indre arteriel indsnævring	1
Asymptomatisk pulmonal emboli efter udtagning	1

Proceduremæssig

Indføring af indføringskateter

1. Vælg en egnet adgangsvej via vena jugularis i enten højre eller venstre side, afhængigt af patientens alderster eller anatomi, kirurgiske præferencer eller placeringen af venøs trombose.
2. Klargør, dræk og anæstesér hudpunkteringssted på standard.
3. Vælg og åbn Recovery Cone Removal System-pakningen. Åbn kit A.
4. Foretag et indsnit i huden med et nr. 11 blad og forstør vævspunktur med en 18 gauge nålepunkteringsnål.
5. Indsæt guidewiren og før den forsigtig frem til Recovery filteret for at lege der.
6. Fjern venepunkturnålen over guidewiren
7. Prædilatér det akutte kar med en 12 Fr. dilatator.
8. Før det 10 Fr. store indføringskateter ind i venen sammen med dets konkave dilatator og guidewiren.

BEMÆRK: Indføringskateteret har en røntgentæt markør i den distale ende af kateteret, den som hjælp ved visualisering

9. Fjern guidewiren og dilatatoren og afbind kateteret med pladsen på det nærmeste sted. Skyl med medicinsk mærket sterilt saltvandsopløsning for at fjerne luft fra kateteret for at undgå indføringskateterets åbning.
10. Foretag et standard venøs cava inferior venogram (typisk 30 ml kontrastvæske med 15 ml/sek.). Kontroller for tromber inden for filter. Hvis der er signifikante tromber i kanal, må Recovery Filteret ikke fjernes

Recovery, konsolindføring og placering

11 Fjern kovolen og skubbesystemet fra Kit B

12 Gennemskyl konsollets centrale lumen og ved kovolen med saltvand - hold heparinsæt ved hånd

13 Træk langsomt kovolen ind i Y-adapteren for at klappe kovolen sammen.

BEMÆRK: Kovolen skal trækkes helt ind i Y-adapteren, for ellers vil det ikke være muligt at skære, at kovolen nemt kan placeres gennem introducer.

14 Tilslut en 50 ml sprøjte med saltvand til sideåbningen på Y-adapteren. Lad saltvandsmassagen lede omhyggeligt gennem Y-adapteren og kovolen. Tilbageslag i sprøjten vil indikere, at kovolen er åben ved enden, men vil ikke være nødvendig, da skubbeskaftet kan føres frem.

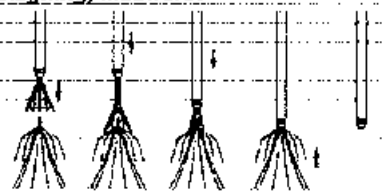
15 Tilbyd kan ender af Y-adapteren til den sammenklappede kovol direkte til indføringsintroducer, indføringsintroducer og Peel-Away-splitter, skal holdes på en lige linje for at minimere friktionen.

16 Indfør kovolen ved at føre de skubbeskaftet frem gennem indføringsintroducer, så kovolen føres fremefter med hele sin længde af skubbeskaftet.

17 Fortsæt med at indføre kovolen med skubbeskaftet, indtil kovolen når frem til den ønskede position på den distale ende af indføringsintroducer. Hold skaftet stille for at klappe kovolen ved at skubbe skaftet og holde introducer tilbage.

Ordning af Recovery Filteret

Filterudtagning, illustreret



18 Ordningen af Recovery Filteret er vist på tegn B-F

Figur B: Når kovolen er åbnet delvis over filteret, føres kovolen over filterspidsen ved at holde indføringshåndtaget stationært og føre skubbeskaftet frem. Det anbefales at 3 til 4 skift anvendes kovolåbne tilskud for at kontrollere, at kovolen glider over filterspidsen.

Figur C: Luk kovolen over over filterspidsen ved at føre indføringsintroducer over kovolen, mens skubbeskaftet holdes stationært.

Figur D: Fortsæt med at føre indføringsintroducer over kovolen, indtil kovolen er inden i indføringsintroducer.

Figur E: Mens kovolen er lukket sammen over filteret, trækkes filteret ved at skubbe skaftet og holde skubbeskaftet tilbage i en jævn, kontrolleret bevægelse.

Figur F: Filteret er fuldstændigt tilbagetrukket

Opfølgende Venografi-undersøgelser

19 Der kan foretages et opfølgende venografi-undersøgelse, så indføringsintroducer er trukket tilbage (typisk 30 cm fjernet fra indføringsstedet).

20 Fjern indføringsintroducer og udfør manuel kompression over punktursstedet på sædvanlig vis for at opnå hæmostase.

Guidewire – Assisteret teknik

På grund af anatomiske variationer med hensyn til placering af Recovery filteret kan der anvendes guidewire-assisteret teknik.

Anvendelse af en guidewire

Hvis det er ønskeligt at lave **Recovery** kovolen lige over **Recovery Filterets** spids, kan man benytte en guidewire for at lette centrering af kovolen over filterspidsen.

Træk indføringsstiften og kovolskaftet tilbage og ind i filterspidsen. Indfør en 0.035" guidewire gennem det centrale lumen (med J-spids eller vinkel spids, det anbefales at anvende en guidewire med hydrofil coating). Før guidewiren gennem kovolen og gennem filterets maskeåbning af filterspidsen..

Efter at det er blevet bekræftet, at guidewiren er i kontakt med eller tæt på filterspidsen, føres kovolen ind over guidewiren til filterspidsen.

Før indføringsstiften frem for at klappe kovolen let sammen over filterspidsen. Træk guidewiren tilbage i det skubbeskaftet.

Fortsæt med at udtage filteret som beskrevet i trin 15.

J. Levering

Hvert **Recovery** Filter leveres sterilt og apyrogent, og beregnet til engangsbrug. Opbevaringsmiljø og indføringssystemet leveres som let. Hvis blisterpakningen åbnes, må man ikke benytte produktet, hvis sterilitet ikke længere er garanteret.

Bemærk: Efter brug kan **Recovery** Filteret betragtes som biologisk farligt affald. Det skal håndteres og bortskaffes i overensstemmelse med godkendt medicinsk praksis og gældende lokale, nationale og føderale love og direktiver.

Recovery Filteret skal opbevares køligt (stuetemperatur) og tørt.

K. Garanti

Bard garanterer over for den første køber af dette produkt, at det er fri for materiale- og fabrikationsfejl for en periode på 45 år regnet fra datoen for første køb, og anbefaler derfor denne begrænsede produktgaranti vil være begrænset til reparation eller udskiftning af det defekte produkt eller, Bards skøn eller refusion af dets købspris eller del heraf. Ændringer tilbage ved brug eller misbrug af det defekte produkt som følge af forkert anvendelse af dette produkt af disse dele af en begrænset garanti.

UDEN OMFANG DET ER TILLADT AF GÆLDENDE LOVE, ERSTATTER DENNE BEGRÆNSEDE PRODUKTGARANTI ALLE ANDRE GARANTIER, UDTRYKTE ELLER UNDERFORSTÅEDE, HERUNDER, MEN IKKE BEGRÆNSET TIL, ENHVER UNDERFORSTÅET GARANTI FOR SALGBARHED ELLER EGNETHED TIL ET BESTEMT FORMÅL. BARD VIL UNDER INGEN OMSTÆNDIGHEDER KUNNE HOLDES ANSVARLIG FOR HÆNDELIGE SKADER ELLER FØLGESKADER SOM FØLGE AF HÅNDTERING ELLER ANVENDELSE AF DETTE PRODUKT.

Visse stater tillader ikke udelukkelse af underforståede garantier, hændelige skader eller følgeskader. Det kan være sandsynligt at yderligere ansvarsfraskrivelser ikke følger af loven i Deres stat/land.

Ekstraudstyrsnummer: 1240

Hvis der er spørgsmål vedrørende denne enhed og produktets brugsdata, bør brugeren kontakte C.R. Bard, Inc. for at kontrollere, om der er yderligere produktoplysninger tilgængelige.

Bard, Recovery og Recovery Cone er registrerede varemærker tilhørende C.R. Bard, Inc. eller et tilknyttet firma.

U.S. Patent Nr. 6 007 558 og 6 258 026. Øvrige patenter anmeldt

Referencer:

1. ACR Standard for The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement for The Prevention Of Pulmonary Embolism - 2006 (Rev. 12). Gældende fra 01/01/01

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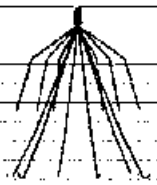
Recovery® Filtersystem för användning i vena cava



SVENSKA

Bruksanvisning

Försiktighet: Enligt federal lag (USA) får denna anordning endast säljas av läkare eller på läkares föreskrift

A. Allmän information

Recovery-filtret representerar en ny generation av venösa ocklusionsanordningar utformade för att förhindra lungemboli. *Recovery*-filtrets unika utformning och material ger en utökad återvinningsförmåga och möjliggör perkutan placering genom en enkel teknik och med en diameter på 7 F med minimal svårighet vid punktionsstället. Placeringsförfarandet ger snabbt och säkert fäste mot väggen.

Den konvexa uppställningen är utformad för att föras in genom dess introducerkateter på 40 cm, med storlek 7 F, med hjälp av en böjlig pusher-tråd av nitinol. En "knuddel" vid ledarens ände är konstruerad så att den för på kompressen och ett lätt segment är konstruerat för att hålla linan och ovanpass fästs "ren" på rätt sätt. Dessa kan paneuter sätter filtret vid pusher-trådens mesial den för in filtret med snetsen först, till kateters distala ände, som är positionerad under den nedersta njurvener. När filtrets spets på mer segmenter, på introducerkatetern kommer filtret att vara positionerat mellan introducerkatetrens nedersta njurvener och filtret kan introduceras. Introducerkatetern och filtret införs sedan pusher-trådens handtag så att filtrets distala kan släppas av och filtret kan fästpass och därmed återgå till sin förutbestämda form. Centreringssystemet gör att *Recovery*-filtret kan fästpass med pusher-trådens och handtag att filtrets ben korsas.

Recovery-filtret är utformat för att fungera som ett permanent filter. När det är klinikt indicerat kan *Recovery*-filtret avlägsnas på lyckat sätt efter implantation i enlighet med anvisningarna under "Alternativ metod för att avlägsna filtret". *Recovery*-filtrets effektiva fäster gör att filtret kan förbli stabilt och minska migration men det kommer fortfarande att vara möjligt att avlägsna filtret. (Se "Alternativ metod för att avlägsna filtret" angående specifika anvisningar för hantering).

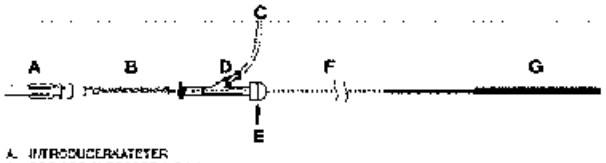
MRT-kompatibel. *Recovery*-filtret är MRT-säkert och kan placeras utan risk för patienten. Se MRT-anvisningar.

B. Beskrivning av anordningen

Recovery-filtersystemet består av filtret och införingssystemet. *Recovery*-filtret består av två nitinoltråd med förminskade spetsar. Från en central förankringsdel. Dessa två trådar bildar två ovaler av ankarfästning benen tillverkade av tråd för förbättrad och säkrare fixering. *Recovery*-filtret är avsett att användas i vena cava med en diameter på upp till 28 mm.

Det avsedda för *Recovery*-filtret visas i Figur A. Införingssystemet består av en introducerkateter med en innerdiameter på 7 F och en dilatator. *Recovery*-filtret, ett förvaringsrör med inlusionsport för koksaltlösning, samt en pusher-system. *Recovery*-filtret är fast på fästpass i införingsröret.

Figur A: Recovery-filtersystem



A. INTRODUCERKATETER
B. NÅL FÖR FLUOROSKOPISK VÄGLEDNING
C. INFUSIONSSETT FÖR KOKSALTLÖSNINGSDROPP
D. SIDOPORT
E. JUSTERBAR TOUHY-BORST-ADAPTER
F. PUSHER-TRÅD AV NITINOL
G. HANDTAG TILL PUSHER-TRÅD

VIKTIGT: Läs anvisningarna noga innan du börjar använda *Recovery*-filtret.

C. Användningsområde

Recovery-filtersystemet är avsett att användas för att förhindra återkommande lungemboli hos patienter för vilka [illegible]

- [illegible]
- På marknaden kombinerade och rekommenderade är kontraindicerade.
- Behandling med antikoagulantia för tromboembolisjukdom har misslyckats.
- Akut blodförtunning eller annan lungembolidiagnostik av konventionell behandling är nödvändig.
- Kronisk, återkommande lungembolidiagnostik med antikoagulantia har misslyckats eller är kontraindicerad.
- *Recovery*-filtret kan avlägsnas enligt anvisningarna nedan under avsnittet "Alternativ metod för att avlägsna filtret".

D. Kontraindikationer

FÖRSIKTIGHET: Om den korrigerade inre diametern hos vena cava inferior överstiger 28 mm får filtret inte föras in i denna ven.

Recovery-filtret skall inte implanteras i:

- Gravida patienter när överskop kan utsätta fostret för fara. Risker och nytta måste bedömas noga.
- Patienter med större vena cava-diameter än 28 mm
- Patienter som löper risk att få septisk embol.

E. Varningar

Implantation av Recovery-filtret

1. *Recovery*-filtret [illegible] för enkelhetens skull. Försök inte att [illegible] filtret innan det har fått korrekt position i vena cava inferior, eftersom *Recovery*-filtret då kan föras in i införingsröret igen på vägen ut.
2. *Recovery*-filtret kan placeras via femoral- eller jugularåtkomst. Om man väljer jugularåtkomst bör man se till att [illegible] kan föras in utan svårighet.
3. *Recovery*-filtret är avsett att användas med det införingssystem som tillhandahålls av C. R. Bard, Inc. Införingssystemet för *Recovery*-filtret är förpackat i en [illegible] för att bibehålla sterilitet. Använd inte införingssystemet för *Recovery*-filtret om förpackningen är öppnad eller skadad. Det kan leda till [illegible] och/eller [illegible].
4. Om det påvisas en [illegible] vena cava måste införingssystemet [illegible] filtret [illegible] att [illegible] införingssystemet [illegible] och [illegible].
5. Använd endast *Recovery Cone* utsugssystem för att avlägsna *Recovery*-filtret. Försök aldrig att avlägsna filtret på nytt.
6. Ledtrådar eller introducerskiljeväggar för aldrig [illegible] och [illegible] införingssystemet [illegible] [illegible].

Avlägsnande av Recovery-filtret

1. [illegible] för att [illegible] filtret om [illegible] filtret eller om [illegible] är [illegible] på vena cava.
2. Använd endast Bard utsugssystem *Recovery Cone* (levereras separat) för att avlägsna *Recovery*-filtret. Användning av andra anordningar har inte fastställts [illegible].

F. Förebyggande åtgärder

Implantation av Recovery-filtret

1. Placera filtret inom [illegible] på [illegible] vena cava [illegible].
2. Anatomiska variationer kan försvåra införing och [illegible] av filtret. Om man följer dessa anvisningar [illegible] kan det [illegible] införingsröret och [illegible] [illegible].
3. Spänn [illegible]. Det är viktigt att vara försiktig när man övervakar [illegible] av [illegible] med betydande fysiologisk [illegible] [illegible] vena cava inferior kan följa samma generella riktning som sådana anatomiska [illegible].

Det kan krävas [illegible] för att avlägsna filtret.

Avlägsnande av Recovery-filtret

1. Anatomiska variationer kan försvåra införing och [illegible] av *Recovery Cone* utsugssystem. Om man följer dessa anvisningar [illegible] kan det [illegible] införingsröret och [illegible] [illegible] för avlägsnandet.
2. Spänn [illegible]. Det är viktigt att vara försiktig när man övervakar att avlägsna *Recovery* filtret med utsugssystemet *Recovery Cone* på patienter med betydande fysiologisk [illegible] [illegible] vena cava inferior kan följa samma generella riktning som sådana anatomiska [illegible]. Det kan krävas [illegible] för att avlägsna filtret.

G. Potentiella komplikationer

- Filtermigration. Det kan [illegible] att filtret placeras i en vena cava med [illegible] större diameter än 28 mm, eller att man använt felaktiga förankringstekniker.
- Perforation av väggen i vena cava. Detta kan uträffa om felaktig införingsteknik används.
- Ocklusion av vena cava. Som riskerna för att detta ska inträffa måste vägas mot de inneboende förhållanden rekommenderas för en patient som fått lungemboli, eller som sannolikt kommer att få det, om inget ingrepp görs.

H. Erforderad utrustning

Följande utrustning behövs:

- Ett *Recovery*-filter och bärsystem som innehåller:
- En 40 cm introducer med innerdiameter 7 F och en dilatator
- En lövgenomgång med flikventil *Recovery*-filter och pusher-system
- 0,035" ledare med 3 mm J-spets, 145 cm lång eller längre
- 18 gauge punktionsnål
- Kokvätskeslang
- Steril förlängningsslang för koksaltlösning eller infusion
- Att beställas för separation: skalpell, injektionsspruta, [illegible], sterilt bordsöverdrag, [illegible], sax, [illegible], etc.
- En punktionsnål [illegible] av en 0,035" ledare med 3 mm J-spets, punktionsnål, [illegible] av 11 och sträcka på 14 cm [illegible]. Satsen kan beställas från C. R. Bard, artikelnummer 4000E.

Om du har valt att använda *Recovery*-filtret genom att kan *Recovery Cone* utsugssystem beställas från C. R. Bard, Inc.

I. Bruksanvisning

Införing av 7 F introducerkateter och [illegible] ventrikel

1. Välj en lämplig ingångsplats [illegible] anatomin på höger eller vänster sida, beroende på patientens storlek och anatomi, längsgående preferenser eller vad som ombesörjs efter.
2. Förbered, [illegible] och bedöva stället för hudpunktionen på vederlaget sätt.
3. Välj och öppna förpackningen. Öppna sats. Använd förpackningen som innehåller introducersystem.
4. Sätta nålen med stickpetskod nr 11 och [illegible] venpunktion med en 18 gauge punktionsnål.
5. Sticknålen med J-spets och [illegible] ledare i den [illegible] vena cava eller vena iliaca.

OBS! Om man stöter på motstånd under en inläggningsprocedur i vena femoralis, se till att man [illegible] att ledaren och kontrollera [illegible] öppenhet [illegible] med en lätt injektion kontrastmedel. Om en sådan [illegible] påvisas, ta bort venpunkteringsnålen och försök med [illegible] på motsatta sidan. Det går eventuellt att gå förbi en [illegible] med ledare och introducer.

6. Avlägsna venpunktionsnålen över ledaren med kvarlämnande av [illegible] i [illegible] med den [illegible] [illegible] över ledaren och in i [illegible] vena cava eller vena iliaca.

OBS! Introducerkatetern har röntgentäta markörer som gör det lättare att se den och underlättar positionering av filtret före inläggning. De röntgentäta markörerna på introducerkatetern utgör "mål" mellan vilka filtret ska positioneras strax innan slidan skalas av och inläggningen.

7. Avlägsna ledaren och dilatatorn, med [illegible] över introducerkatetern med spetsen i [illegible] vena cava eller vena iliaca. Spola [illegible] [illegible] över ledaren och [illegible] [illegible] till [illegible] för att hålla introducerkatetern öppen.

OBS! Introducerkatetrens fästning har en special sorts utformning. Var noga med att skruva åt kopplingarna ordentligt, men se inte till så mycket att fästningen går sönder.

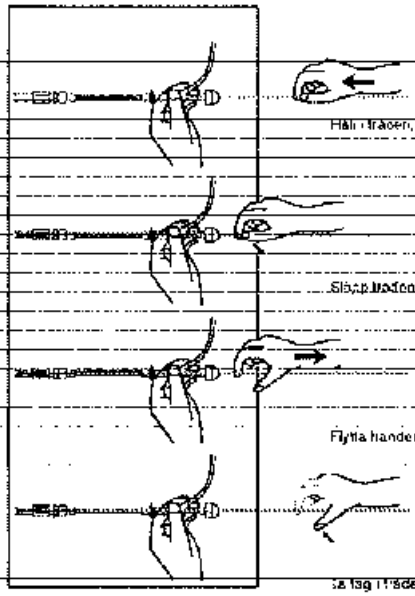
8. Utför en vanlig cavagram av vena cava inferior (normalt 30 ml kontrastmedium vid 15 ml/s). Kontrollera om det finns kontrast i vena cava, njurvenernas läge och medfödda missbildningar. Välj optimal nivå för filterplacering och mät diametern i vena cava inferior, med förstoringskorrektion (normalt 20 %).
9. För introducerkatetern, [illegible] den utvalda nivån under fluoroskopisk kontroll. För att underlätta detta skall ledaren och dilatatorn föras samtidigt. Vid införing kontrollera att introducerkatetrens spets ligger 1 cm nedanför den nedersta njurvenen.
10. Ta ut ledaren och bärsystemet från sats B.
11. Anslut en 500 ml-påse med koksaltlösning till exporten på Y-adaptern med det vanligt använda förpackningen. Låt koksaltlösningen flöda runt filtret i förvaringsröret i 10 sekunder så att det mjukas upp innan passagen genom introducerkatetern. Justera infusionshastighet till en snabb droppfrekvens. Det är viktigt i Touhy-Borst-adaptern för att minimera reflux av koksaltlösning, men se till så att systemet inte är för tätt så att [illegible] kan föras in lätt.

OBS! Det är mycket viktigt att hålla introducerkatetern öppen med koksaltflöde så att det nitinola segmentet som hålls [illegible] inte fastnar. Detta hindrar införingsröret att [illegible].

12. Fäst en [illegible] på filtrets förvaringsrör. Dra [illegible] med introducerkatetern som redan finns i venen, vilket gör att koksaltlösningen kan [illegible] i vena cava inferior i några sekunder. Håll introducerkatetern och filtersystemet i en rak linje för att minimera friktion.

Införing av filtret, illustration

FIGUR B



FIGUR C

FIGUR D

FIGUR E

13. För in filtret genom att flytta pusher-tråden av rilsvit framåt genom introducentslementet, och för in filtret med vena femoralisvenen med pusher tråden (figur B). Om inte tillräcklig pushet tråden, för den endast framåt. För bekvämlighet, skall och för att underlätta hantering och införing av pusher tråden kan man vara upp pusher tråden av hänvisningsmärket så att det bildar linjer på referensmärket.
14. Fortsätt att föra in pusher-tråden tills klaspetsen når fram till den föregående markören på pusher tråden, dvs tills änden av introducentslementet. Nu bör pusher-trådens handtag vara stående mot Y-adaptern.

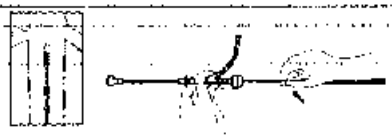
Frisläppning av filtret

15. För in och frisläpp filtret så som beskrivs nedan:
    - Figur F: Det återstående pusher-trådens handtag
    - Figur F-1: Efter positionering av introducentslementet i nedre om det föregående markörens läge frisläppning vena cava inferior.

OBS! För inte in filtret förbi änden på introducentslementet. Skada i stället av skadan på det stationära filtret genom att dra ut introducentslementet så som beskrivs nedan.

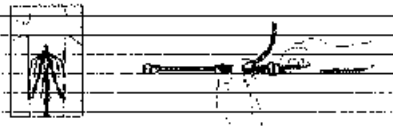
Frisläppning av filtret, illustration

FIGUR F
FIGUR F-1



FIGUR G
FIGUR G-1

FIGUR H
FIGUR H-1



Frisläpp filtret nu genom att dra av skaden inne i vena cava inferior på följande sätt:

Positionera tillmätspetsen 1 cm nedanför den nedersta rejnmarken.

Figur G: Håll ena handen stilla. Dra med andra handen tillbaka Y-adaptern och filtret tillräckligt över handtaget, vilket gör att filtret avlägsna och frisläpps.

- Figur G-1: Filtret skall skalas av i vena cava inferior.
- Figur H: Händernas position då avlastningsprocessen är klar.
- Figur H-1: Tillbaka frisläppt i vena cava inferior.

16. Dra nu tillbaka pusher-tråden och Novaray-gaster genom att hålla stadigt Y-adaptern förvarsgaster och införingsstället och samtidigt dra i pusher-tråden.
17. Återuppta det intermittenta heparinflödet eller den kontinuerliga droppinfusionen för att hålla intravenen öppen.

Upplösande rintgen av vena cava (venacavagram)

18. En upplösande röntgenundersökning av vena cava (venacavagram) kan utföras för introducentslementet dragits ut i vena cava (normalt 30 ml kontrastmedium vid 15 ml/s).
19. Ta bort introducentslementet och tillämpa tillräckligt kompression över punkteringsstället för att uppnå hemostas.

ALTERNATIV METOD FÖR ATT AVLÄGSNA FILTRET:

Avlägsnande av Recovery-filtret

FÖRSIKTIGHET: Recovery-filtret ska endast avlägsnas med användning av Recovery Cone.

Erforderlig utrustning

Följande utrustning erfordras:

- Ett Recovery Cone-utlägsnandesystem (innehåller:
- Lokalbedövningsmedel (rekommenderas 10 ml 1%)
- En introducer med Recovery Cone och pusher-system
- 0,035" ledare (med 3 mm J-spets, 175 cm lång eller längre
- 18-gauge punktionsnål
- Dilator, 12 French
- Kateterisering
- Sterilt förbindningsmaterial för kirurgisk drog och sterila kirurgiska instrument
- Ett lämpligt system för visualisering av filtret, t.ex. fluoroskopiutrustning, operationsbord, mm

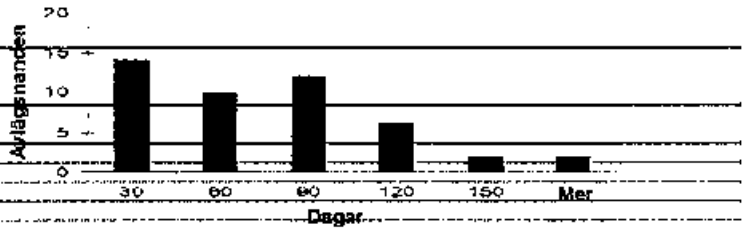
Klinisk erfarenhet

Recovery-filtret har utvärderats i kliniska prövningar av privata och två kollegor vid sex sjukhus i Nordamerika på 52 patienter, enligt nedanstående påvisningsbild:

Även om det endast var en liten del som fick undersökningen som en del av undersökningen av de större medicinska typer av klinisk och avlägsningsförsök.

Av de 52 implanterade filtren har totalt 46 avlägsnats, 6 sitter kvar på plats, och 4 patienter har avlidit med filtret kvar av skäl som inte är relaterade till implantering eller avlägsnande (cancer, emfysem, polyartrit och lungsvikt). Hälften av avlägsnandena utfördes mellan 1 och 151 dagar med ett genomsnitt på 60 dagar (se histogram).

Tid fram till avlägsnandet



Upplösningen av avlägsnade filter medför mer än 90 dagar (omfång 1–801 dagar). De flesta (ca 4/5) avlägsnades vid tidpunkter inom, men ett par har påträffats vid tider vara upptäckta inom (n=1) och en tidigare vara upptäckt (n=1). En patientgrupp var på en observationsstudie av tumörer rörliggande på filtret. De två patienterna som fick tumörer hade en användbar tid av 6 månader och 4 år, en stöld introducer användes, eller de inom 2 månader efter att filtret hade satts in. Ett filter har observerats med tumörer på den övre delen av det. Recovery Cone-systemet. En halv observerades med tumörer på filtrets övre del av det.

Den vanligaste enskilda orsaken till upptäckt av en tidigt återgående och rör. Detta filter är gjorde. Trängsel på en gräddkonna kunde både bredden vid kontakt. Trängsel kunde vara allvarlig. En patientgrupp och patientgrupp filtrerades, vilket kostar för avlägsnande och införing av broken. Patientgrupp kunde. Filter togs av, minus tråden.

Sammanfattande tabell över klinisk erfarenhet	
Implanterade Recovery-filter	
Perkutana avlägsnanden av filter	45
Kirurgiska avlägsnanden av filter	1 (i samband med tumörresektion)
Patienttider	8–69 år (genomsnitt 52 år)
Skäl till filterplacering	
Kontraindikation mot antikoagulation	40
Komplikationer förknippade med antikoagulation	13
Misslyckad antikoagulation	3
Profylax	2
Tid fram till avlägsnandet	1–151 dagar (genomsnitt 60 dagar)
Upplösning efter avlägsnande	1–801 dagar (genomsnitt 225)
Komplikationer vid avlägsnande av filter	
Tekniska	1
Kräver akut sekundärt ingrepp/åtgärd på grund av	
Förlossning och införande placering	1
Asymptomatisk lungembolisering efter avlägsnande	1

Anvisningar för ingreppet

Införing av introducentelementet

1. Välj en lämplig ingångsplats i jugularis venen antingen på höger eller vänster sida beroende på patientens storlek och anatomi, kirurgens preferenser eller var venen bäst är.
2. Förbered, drapera och bedöva stället för hudpunkteringen på vederbörligt sätt.
3. Välj och öppna förpackningen med Recovery Cone-kateter. Öppna sedan introducentsystemet.
4. Sticka nålen med en lätt lutning på 11 och 45° mot patienten med en ingångsvinkel mellan 15
5. Sticka in ledaren och för försiktigt in den till nivån där Recovery-filtret kommer att placeras.
6. Avlägsna nålen/dilatorn över ledaren.
7. Förstärka ingångsplats med en 12 French dilator.
8. För en införingsslang med diameter på 10 Fr tillsammans med dess avsmalnande dilatator över styrtråden och in i kärlet.

OBS! Introducentsystemet får en avsmalnande mantel vid spetsen som gör det lättare att se den.

9. Avlägsna ledaren och dilatorn, men lämna kvar introducentsystemet med spetsen på lämplig plats. Spola omedelbart för hemostas genom en kontinuerlig droppinfusion med heparinlösning för att förhindra trombosering av kärlet.
10. Utför en enkel röntgenbild av vena cava inferior (normalt 30 ml kontrastmedium vid 15 ml/s). Kontrollera om det finns tecken på filtret. Om det finns befarande införingsproblem i filtret, ska Recovery-filtret inte avlägsnas.

Införing och kvarlåtande av Recovery Cone

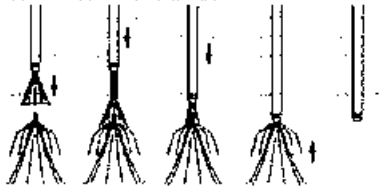
11. Ta ut konen och införingssystemet ben sats B.
12. Spola kanülsystemets centrala lumen och vik konen mot hårsäljöring – håll hopvikt med sidor.
13. Dra sakta tillbaka konen i Y-adaptern för att kollabera konen.

OBS! Konen måste vara fullständigt indragen i Y-adaptern innan du kopplar systemet till introducerkatetern för att garantera att konen lätt kan föras in genom kateter.

14. Anslut, en SIK mjukslang eller en sprutla med koksaltlösning till sidporten på Y-adaptern. Låt koksaltlösningen flöda mot motorn, men inte så hårt att patienten inte kan tåla mängden.
15. Anslut handdonen på Y-adaptern med den kollapsade konen direkt till introducerkatetern. Introducerkatetern och konen är systemen ska hållas i en nära linje för att minimera friktion.
16. För in konen genom att trycka på den framåt genom introducerkatetern, vänd för in konen med viss framåtriktning med pusher.
17. Fortsätt att trycka genom framåt tills konen kommer fram till den röntgentäta markören på den distala änden av introducerkatetern. Dra av slidern för att öppna konen genom att stabilisera skaftet och dra tillbaka katetern.

Införingande av Recovery-filter

Avlägsnande av filter, illustration



18. Införingsstav av Recovery-filtret visas i Figur B–F.

Figur B: När konen öppnats ovanför filtret, för in stavens konus över filterspetsen genom att hålla introducerkatetern stadig och föra pushern framåt. Det rekommenderas att använda en vätskefylld sprutspruta för att bekräfta att konen ligger över filterspetsen.

Figur C: Sänk konen över filterspetsen genom att föra framåt introducerkatetern över konen medan du håller pushern stadig.

Figur D: Fortsätt föra framåt introducerkatetern över konen tills konen är över introducerkatetern.

Figur E: När konen kollapsat över filtret, avlägsna hela genom att stabilisera introducerkatetern och dra tillbaka pushern och ende-andig fjäril rörelse.

Figur F: Filtret har avlägsnats från kärlet.

Upprepande röntgen av vena cava (venacavogram)

19. En upprepande röntgenundersökning av vena cava (venacavogram) kan utföras när introducerkatetern dragits ut internalt SK mjukslangsmedium vid 15 ml/sek.
20. Avlägsna introducerkatetern och tillämpa extremitetskompression över punktionsstället för att uppnå hemostas.

Ledare (tillval tillval)

På grund av anatomiska variationer med avseende på Recovery-filtrets position, kan ledare ibland användas för att hjälpa till att föra konen över filterspetsen.

Användning av en ledare

Om det är svårt att föra fram Recovery Cone-systemet över Recovery-filtrets spets, så kan en ledare användas för att göra det lättare att föra konen över filterspetsen.

Dra bort introducerkatetern och kontrollera läge för filterspetsen. För in en 0,035" ledare genom det centrala lumenet (hopvikt eller sammanfallet) spets, en ledare med hydrofil beläggning rekommenderas). För in ledaren genom konen och genom filtret över filterspetsen.

När du bestämt att ledaren är innanför eller i närheten av filterspetsen så för du in konen över ledaren till filterspetsen.

För introducersystem framåt för att inrätta konen något över filterspetsen. Dra tillbaka ledaren och pusher.

Fortsätt avlägsna filtret enligt beskrivningen ovan, fig. H.

J. Leveransform

Alla Recovery-filter levereras förkonfigurerade i sina förpackningar. Alla Recovery Cone-filter är sterila och pyrogenfria, förutsatt att förpackningarna är oöppnade eller skadade, och är endast för engångsbruk. Förvaringsrör och bäraresystem är förlängarmare sida. Om filtret oavsiktligt skulle förskjutas, så får det inte repositioneras eller fästas på nytt.

Obs: Efter användning kan Recovery-filtret farligt och särskilda bestämmelser utgöra potentiellt biologiskt riskmaterial. Hanteras och kasseras det i enlighet med medicinsk praxis och gällande lagar och förordningar.

Recovery-filtret ska förvaras svalt (rumstemperatur) och torrt.

K. Garanti

Bard garanterar återförsäljaren av denna produkt att produkten är fri från defekter i material och tillverkningssätt under den period på sex (6) från inköpsdatumet för återförsäljaren. Enligt denna begränsade produktgaranti är återförsäljarens enda och begränsade kompensation efter köpet av den defekta produkten, enligt Bards egen bedömande, eller återbetalning av enligt ovanstående. Ytterligt förlorad eller skador som uppkommit på grund av felaktig användning av produkten täcks inte av denna begränsade garanti.

ON DET ÄR TILLÅTET ENLIGT GÄLLANDE LAG ERSÄTTER DENNA BEGRÄNSADE PRODUKTGARANTI ALLA ANDRA GARANTIER, UTTRYCKLIGA ELLER UNDERFÖRSTÅDDA, INKLUSIVE, MEN EJ BEGRÄNSAT TILL: ALLA UNDERFÖRSTÅDDA GARANTIER OM KVALITET ELLER LÄMPLIGHET FÖR ETT VISST SYFTE. UNDER INGA OMSTÄNDIGHETER ÄR BARD SKYLDIGT ATT ERSÄTTA DIG FÖR OFÖRUTSEDDA SKADOR ELLER FÖLJDSKADOR SOM UPPSTÅR TILL FÖLJD AV DIN HANTERING ELLER ANVÄNDNING AV PRODUKTEN.

Vissa delstater/länder är det inte tillåtet att utesluta underförstådda garantier eller begränsningar av följdskador. Du kan ha rättigheter till ytterligare kompensation enligt lagarna i ditt delstat/ditt land.

Märkningens utgångsdatum: 12-09

Om det skulle ha gått 3 år mellan detta datum och produktanvändningen, kontakta Bard för att höra efter om ytterligare produktinformation är tillgänglig.

Bard, Recovery, och Recovery Cone är inregistrerade varumärken som tillhör C. R. Bard, Inc. eller en till dem anknuten företagare, USA patent nr 5 007 868 och 6 258 026. Andra patentsökningar är pågående

Källhänvisningar:

1. ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism. 2009 (Res. 18). Effective 01/01/01

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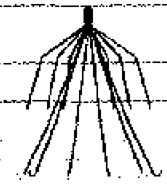
Crawley, UK
RH11 9BP

Onttolaskimossa käytettävä Recovery®-suodatinjärjestelmä



SUOMI

Käyttöohjeet

Huomautus: Yhdysvaltain lain mukaan tätä tuotetta saa myydä vain lääkäri tai lääkärin määräyksestä.

A. Yleiskuvaus

Recovery-suodatin [illegible]

[illegible]

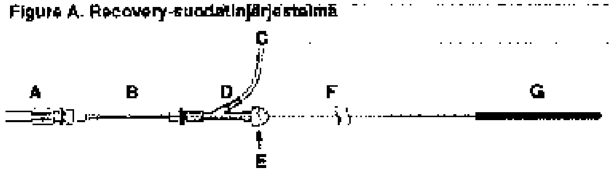
Recovery-suodatin [illegible]

Magneettikuvaukseen liittyvät tiedot: *Recovery*-suodatin on turvallinen käyttää magneettikuvauksissa, eikä se häiritse [illegible]

B. Laitteen kuvaus

[illegible] *Recovery*-suodatin [illegible]

Figure A. Recovery-suodatinjärjestelmä



A. SISÄÄNVIEJÄ
B. SUODATTIMEN SÄILYTYSPUTKI
C. [illegible]
D. SIVUPORTTI
E. SÄÄDETTÄVÄ TUOHY-BORST-SOVITIN
F. [illegible]
G. TYÖNTÖJOHTIMEN KAHVA

TÄRKEÄÄ: Lue ohjeet huolellisesti ennen Recovery-suodattimen käyttöä.

C. Käytön indikaatiot

Recovery-suodatinjärjestelmä [illegible]

- Keuhkoembolia [illegible]
- Antikoagulanttihoito [illegible]
- [illegible]
- [illegible]
- *Recovery*-suodatin voidaan poistaa [illegible]

D. Kontraindikaatiot

VAROITUS: Jos alaonttolaskimon korjattu sisäläpimitta on yli 28 mm, suodatinta ei saa asettaa alaonttolaskimoon.

Recovery-suodatinta ei saa asettaa:

- [illegible]
- Potilaille, joiden onttolaskimon läpimitta on yli 28 mm.
- Potilaille, joilla on septinen embolian vaara.

E. Varoitukset

Recovery-suodattimen implantaatio

1. *Recovery*-onttolaskimosuodatin on tarkoitettu [illegible]
2. Recovery-suodattimen [illegible]
3. Recovery-suodatinjärjestelmä on [illegible] *Recovery*-suodatin [illegible]
4. Jos [illegible]
5. Recovery-suodattimen poistamiseen [illegible] *Recovery Cone*-poistojärjestelmää. [illegible]
6. [illegible]

Recovery-suodattimen poistaminen

1. Älä yritä poistaa *Recovery*-suodatinta [illegible]
2. Käytä vain Bardin *Recovery Cone*-poistojärjestelmää [illegible]

F. Varotoimenpiteet

Recovery-suodattimen implantaatio

1. Suodatin tulee asettaa [illegible]
2. [illegible]
3. [illegible]

Recovery-suodattimen poistaminen

1. [illegible] *Recovery Cone*-poistojärjestelmän [illegible]
2. [illegible] *Recovery Cone*-poistojärjestelmän [illegible]

G. Mahdolliset komplikaatiot

- [illegible]
- Onttolaskimon seinämän perforaatio. [illegible]
- Onttolaskimon tukos. [illegible]

H. Tarvittava välineistö

Toimenpiteessä tarvitaan seuraavia välineitä:

- Yksi *Recovery*-suodatin ja asennusjärjestelmä, jossa on:
  - [illegible]
  - [illegible] *Recovery*-suodatin ja työntöjärjestelmä
- [illegible]
- 18 G:n punktioneula
- Lisävarusteet:
  - [illegible]
  - [illegible]
  - [illegible]
  - [illegible] C.R. Bard [illegible]

Jos [illegible] *Recovery*-suodattimen [illegible] C.R. Bard [illegible] *Recovery Cone*-poistojärjestelmä.

I. Käyttöohjeet

7 F:n [illegible]

1. [illegible]
2. [illegible]
3. [illegible]
4. [illegible] 18 G:n punktioneulalla.
5. [illegible]

HUOMAUTUS: [illegible]

6. [illegible]

HUOMAUTUS: [illegible]

7. [illegible]

HUOMAUTUS: [illegible]

8. [illegible]
9. [illegible]
10. Poista suodatin ja asennusjärjestelmä [illegible] B.
11. [illegible]

HUOMAUTUS: On erittäin tärkeää pitää sitkämäkeä ja voimakasta kiristysvoimaa suodattimen avulla, jotta suodattimen jalkoja pitävä ja ne suuntaava uralleen osa ei hajoa leikkauksen aikana.

12 Kiinnitä suodattimeen pysyvästi pitävä pidikkeen suunnassa olevaan sisäänvientiin ja aseta sellaisenaan tai vaadittaessa ohjeistuksen mukaisesti sopivan pituiseksi leikattu suodatinputki. Sisäänvientiä ja suodattimen asennusjärjestelmä on pidettävä suorassa linjassa ennen lukitsemista.

Suodattimen kuljettaminen eteenpäin, kuvat

KUVA B

Tartu vaijerin työkenno eteenpäin

KUVA C

Vapauta vaijeri

KUVA D

Siirrä kättä taaksepäin

KUVA E

Tartu vaijerin uusikseen

13 Ala suodattimen asennusta eteenpäin työntämällä suodattimen kärkeä eteenpäin vain suodattimen eteenpäin työntämisen jälkeistä eteenpäin suuntautuvaa liikettä (kuvat E–E). Työntämisessä ei saa vetää taaksepäin, sillä se irrottaa vain eteenpäin. Työntämisen voiman lisäksi ja suodattimen helpottamiseksi käytä samalla imua, että suodatin on tiukasti.

14 Jatka työ edellä tehdyn tarkkaasi eteenpäin, kunnes suodattimen kärki saavuu osalle, jossa suodattimen pää on irrotettavissa olevan röntgenpositiivisen merkin kohdalle. Tässä vaiheessa työntöjohtimen kahvan tulu olla Y-sovittimen lähellä.

Suodattimen vapauttaminen

*5 Aseta suodatin lukitsemaan seuraa-asi:

Kuva F: Erillä työntöjohtimen kahvasta irrotetut kuva

Kuva F-1: Suodattimen sisäisä suodattimen irrotuspalkeiden sarjaan välissä erinäisen aseta alaosalla aloitettaessa on

HUOMAUTUS: Suodatinta ei saa asentaa työntämällä se ulos alaosaviljasta. Katetrissa ajoitetaan suojatin on asennettava pa jotkeen voimakkaita sisäänvirtaja tarkoituksen aiku annetujen ohjeiden mukaisesti.

Suodattimen vapautus, kuvat

KUVA F
KUVA F-1

Vedä kaksi taakse

KUVA G
KUVA G-1

Pidä kättä paikallaan

KUVA H
KUVA H-1

Suodatin vapautetaan vapauttamalla se alaonttolaitteesta seuraavasti:

Aseta alaonttolaitteen kädet 1 ja 2 on liitetään toimintalaitteeseen alapuolelle.

Kuva G: Seuraile kun laitetta kättä pidetään paikallaan, laitetta kädellä vedetään Y-sovitin ja säilytysputki kevyin laskee kahvan päälle, jolloin suodatin vapautuu.

Kuva G-1 Suodattimen vapautuminen alaonttolaitteesta

Kuva H: Kiksun asetin, kun suodatin on vapautettu.

Kuva H-1: Suodatin asennettuna alaonttolaitteeseen

16 Vedä nyt työntöjohdin toisen säilytysputken pitämällä laitetta kuin Y-sovittimen, säilytysputken ja asennuslaitteen yläosasta ja vetämällä laitteen työntöjohdinta

17 Jatka sitten eli hävitetään tarpeeton ylimääräpituus katetrin ulkoiselle, jotta sitä voidaan pitää yllä.

Uusi antitrombiinin vaijaimenkäyttöaika

18 Jos embolisaation vaijaimenkäyttöaika vaatii sen jälkeen, kun asennuspä- ei vaadita lopullisen asennuksen ilypitävät 20 ml vaijaimella vapaudella 15 m/s)

19 Poista asennuspä ja käytä pantiokohdassa tehtävän asennuksen tavallisen tapaan veremenetyksen tarkkailemiseksi.

SUODATTIMEN VALINNAINEN POISTOMENETELMÄ:

Recovery-suodattimen poistaminen

VAROITUS: On erittäin suositeltavaa, että Recovery-suodattimen poisto tehdään ainoastaan Recovery Cone -poistojärjestelmää käyttämällä.

Tarvittava välineistö

Toimenpidettä tarkkaan seuraavia välineitä:

- yksi Recovery Cone -poistojärjestelmä -pakkaus
- yksi 70 cm:n, sisähalkaisijaltaan 16 Fr:n sisäänvientiä helpottava introduceri
- yksi 5 Fr:n ja Recovery Cone -katetrisovitin (Y-sovitin)
- 0,035 tuumaa 3 mm J-kärkinen ohjainvaijer, pituus vähintään 180 cm
- 10 Gn puukotuskatetri
- 18 Fr:n angiogram
- kontrastiväline
- steriili, sakeutettu hydroxietyylipuuroa tai muuta sopivaa kontrastiaineesta vapaata väliainetta
- kaksi sakkuspuristinta tai muuta vastaavaa laitetta, esim. 12 kpl, joka sisältää yhden kokoisen ja

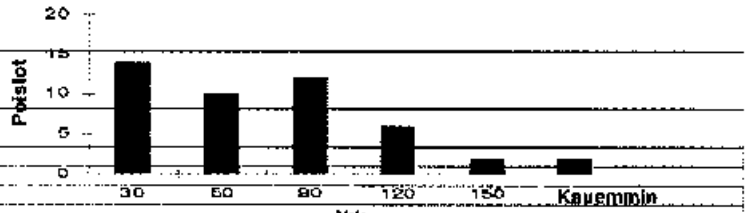
Kliininen kokemus

Ennen tutkijat ja lääkärit ovat suositeltavaa, että he ovat saaneet koulutusta käytä Recovery-suodatin 88 poistoa SA (Special Access) -tutkimuksessa.

Vaikka vain yksi lääkäri vastaanotossa käytettäessä, sen poistamiseen ei mukana kolme lääkäriä, on lääkäreillä ja hoitajilla

Asennetuista 86 suodattimesta 46 poistettiin. 8 on edelleen paikallaan ja 4 potilaalle ruoti suodattimen aikana paineen suodattimen asentamisella tai poistamisessa ja ruumiinosissa syötä (leukemia, sydän, pohjaonteet, keuhkojen ateroskleroosi ja hemorragiat aivohalvaus). Aika suodattimen poistamisen vaihteli 1–161 vrk (keskiarvo oli 40 vrk (5 ja 95 vaihtoväli))

Aika poistamiseen



Poisto on tehtävä suodattimen pa-

Iteisen jäkeen keskimäärin 325 vrk (1–901 vrk). Seuraavia (n=43) potilaita, joiden asennusta kuitenkaan ei ole vielä poistettu vastaavan asennuksen kesäkuukaudesta (n=1) ja ennakoidun kuolemaan (n=1). Yksi potilas ei ole poistettu syystä, että syöpäkudokset levittyivät suodattimen pääle. Kahta käytön jälkeen ilmenneestä suodattimen poistamisen vaikeus potilaalta, jossa käytetyn suodattimen sivuista tarjoaa Recovery Cone -poistopaketin sisältä yritetiin käyttää tarkoituksenmukaisia. Seuraavissa kuvissa käytettiin menetelmiä käytetin apuna.

Tämän lisäksi seuraa lisäkuvauksia tapauksista, joissa suodattimen ei onnistu. Tämä suodatin oli asetettu laskimoon alaosa L3–L4-tasolle viimeisen kokeiluttamisen jälkeen. Potilaan kuolemaan johtaneen munuaisen ala-osassa ja paikallaan asettamisesta aiheutuvan stenoosi saattaisivat jolleivät aikaa laskeutuneet syvä pohjan pakkaisia ja pulmonaalisen luukuvaan asetin. Suodatin poistettiin, koska e.

Yhteenveto taulukko kliinisestä kokemuksesta	
Recovery-suodatinta implantoitu	58
Suodatinta poistettu potilaaseen	45
Suodatinta poistettu kokeiluun	1 (tuumaresektion yhteydessä)
Potilaan iät	8–83 vuotta (keskimäärin 36 vuotta)
Syy suodattimen asettamiseen	
Antikoagulaatio toimimaton	46
Antikoagulaation komplikaatiot	10
Antikoagulaation epäonnistuminen	3
Profylaksi	2
Aika poistamiseen	1–161 vrk (keskimäärin, 40 vrk)
Poistamisen jälkeen seuranta	1–901 vrk (keskimäärin 325 vrk)
Suodattimen poistamiseen liittyvät komplikaatiot	
Tekninen	0
Kuolan murtuma synnyttämisen ja synnyttämisen aikana	
murtuneen alle vuoden aikaisemman stenoosin seurauksena	1
Poistamisen jälkeinen asymptomaattinen tromboosi	1

Toimenpiteen liittyvä arviointi

Sisäänvientiin sisäänviemisen

1. Valitse oikea sisäänvientiväline: Aseta tai asennettu potilas polvan kuin tai sisäänvien, tämänpäivän tekijän valinnan tai laskimoonboosan perusteella.
2. Valmistele ihon punktiokohta, aseta siihen leikkausliinoja ja puudura se tarvittaessa tapaan
3. Valitse ja ota Recovery Cone -valmispakkaus. Avaa Super A steriili-tarkoituksia
4. Tee ihon viilto noin 11 leikkausterällä ja tee laskimopunktio 18 Gn sisäänvientineulalla.
5. Vie ohjainvaijeri sisään ja vie sitä vasemmalle alaonttolaitteen Recovery-asennuksen suodattimen poistamista varten
6. Poista laskimopunktioneula ohjainvaijerin päältä.
7. Esitäytetyn käyttöliitä suoni 12 Fr:n laajentimella.
8. Vie 10 Fr:n sisäänvientiväline yli johtimen ja ohjainvaijerin kunnes jäädöä pitkä laskimoon

HUOMAUTUS: Sisäänvientiin kohdan sisäänvientiä päässä on röntgenpositiivinen merkki tarkkaan kaipottamiseksi.

9. Poista ohjainvaijeri ja suojaimen ja jätä sisäänvientiin ja sen tiiviit asennuksen kohtaan. Huomaa ajoitaan käsi tai kiinnitä suojaimen sisäänvientiin pitämä nippuneuloin asennuksen ja ohjainvaijerin yläpäähän.

10 Tee aloituksi asennusta tarkkaan varjoainevalvonnassa (esim. fluoroskopian avulla) ohjattaessa 30 ml varjoainetta nopeudella 15 ml/s. Tarkista että suodatinosassa ei ole tromboja. Jos suodatinosassa on merkittävä määrä jäätä poista Recovery-suodatin.

Recovery-suodattimen asettaminen ja paikoilleen saattaminen

11 Poista kartio ja työntöputki kohdasta B.

12 Huuhtele kaikki ilmakuplat pois kartiosta ja työntöputkesta keittosuolaliuoksella vaihtamalla ruiskuja.

13 Vedä kartio hiussa Y-sovittimen, jotta kartio suojaa.

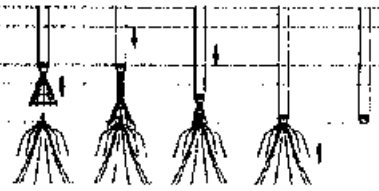
HUOMAA: Kartio on vedettävä kokonaan Y-sovittimen läpi poistettaessa ilmakuplia sisäänvirtausjohdosta, jotta kartio on helppo vetää pois ennen suodattimen laskua.

14 Liitä sentti-Loc sisäänvirtausjohto Y-sovittimen sivuporttiin. Aseta kierrosventtiili avoimeksi. Y-sovittimessa oleva ilmaventtiili sulkeutuu automaattisesti. Kierrä Touhy Borst -sovitinventtiili avoimeksi, jotta keittosuolaliuos täyttää sisäänvirtausjohdon ja Y-sovittimen. Sulje Touhy Borst -sovitinventtiili avoimeksi, mutta ei vielä kokonaan, ettei ilmakuplia pääse ilmaventtiilin kautoon.

15 Liitä Y-sovittimen keskiosaan valuta pää ja suojatu kärki suoraan sisäänvirtausjohdon. Sisäänvirtausjohdon asettaminen ja suojatun kärjen poistaminen suojatun kärjen ympäri.

16 Vie kärkiosa alempaan sisäänvirtausjohdon ja alempaan sisäänvirtausjohdon läpi työntämällä kärkiosa pitkälle työntöputken alempaan ilmaventtiiliin.

17 Vedä työntöputken varressa oleva pieni kärkiosa kartion sisäänvirtausjohdon läpi ja poista kärkiosa työntöputken varresta. Poista ja hävitä kärkiosa steriilisti vasta ennen käyttöä.



Recovery-suodattimen tartuminen

Suodattimen poisto, kuvat

18 Recovery-suodattimen poistaminen on esitetty kuvissa B–F.

Kuva B: Kun kartio on avattu suodattimen yläpuolelta, vie kartio suodattimen kärjen päälle pitämällä suojattua kärkeä pitkällä työntöputken ja viemällä työntöputkea eteenpäin. On suositeltavaa ottaa röntgenkuva suodattimen asennosta, jotta voidaan varmistaa, että kartio on suodattimen kärjen päällä.

Kuva C: Sulje kartio suodattimen kärjen päälle vetämällä sisäänvirtausjohdon kartion päälle ja pitämällä suojattu työntöputki paikallaan.

Kuva D: Jätä suodattimen vierestä kartion päälle, kunnes kartio on suojattuna suojattu.

Kuva E: Kun kartio on suojattu suodattimen päälle, poista suojattu työntöputki ja vetämällä työntöputki varovasti pois (kartio pysyy suojattu kärjen päällä).

Kuva F: Suodatin on nyt poistettu sisäänvirtausjohdon.

Uusi entfolaatimen varjoainevalvonnassa

19 Jos suodatinosassa varjoainevalvonnassa voidaan tehdä sen jälkeen, kun suodattimen on vedetty pois (tyypillisesti 30 ml varjoainetta nopeudella 15 ml/s).

20 Poista suodattimen käytä puhdistamiseen vedellä ohjeissa ja toimitetaan tarpeen veenvuodon tyhjentämiseksi.

Ohjeiden käyttäminen tietokoneella

Koska Recovery-suodattimen pieniä ja vahvoja ominaisuuksia on pohdittu monien vuosien, kokemuksessa vedoksen käytöä ohjeiden avuksi ja tietoa.

Ohjeiden käyttö

Jos kartio on vaihtanut vedä Recovery-suodattimen kärjen päälle, ohjeenvaiheita voidaan käyttää helpottamaan kartion vientä suodattimen kärjen päälle.

Vedä sisäänvejän halkaisijaltaan pienempi kuin 0,035" ohjeenvaiheen kautta kartion läpi ohjeenvaiheen kärjen ulkopuolelle. Kiinnitä kartion, hydrofiilisellä pinnoitteella päällystetty ohjeenvaiheen osa kiinnitetään. Vie ohjeenvaiheen kartion läpi ja suodattimen läpi. Vedä suodattimen kärkeä.

Kun on varmaa, että ohjeenvaiheen kosketus suodattimen kärkeä ja on sen sisällä, vie kartio ohjeenvaiheen pitkin suodattimen kärkeen.

Vie sisäänvejän halkaisijaltaan pienempi kuin 0,035" ohjeenvaiheen kautta kartion läpi ja suodattimen läpi. Vedä suodattimen kärkeä.

Jatka suodattimen poistamista vaiheessa 16 kuvailtu tavalla.

Varoitukset

Recovery-suodattimen käyttäjän välttämättömyyden asiantuntijat. Recovery-suodattimet ovat steriilejä ja pyrogeenittomia, jos pakkaus ei ole avattu tai vaurioitunut. Älä käytä tuotetta, jos pakkaus on vaurioitunut. Suodatinosa on tarkoitettu vain kertakäyttöön. Älä käytä uudelleen, uudelleenkäsittele tai steriloi uudelleen. Uudelleenkäsittely (esim. puhdistus, desinfiointi tai sterilointi) voi aiheuttaa tuotteen rakenteellisen eheyden heikkenemisen ja/tai toiminnan epäonnistumisen, mikä voi aiheuttaa potilaalle vammoja, sairauden tai kuoleman. Uudelleenkäsittely voi myös aiheuttaa kontaminaatioriskin, esim. potilaalta potilaalle tarttuvien infektioiden siirtymisen.

Huomautus: Käytön aikana Recovery-suodattimen laskimoverta ja asennuksen aikana on pidettävä tiukasti kiinni. Välttämättä on käytettävä ja se on hävitettävä Recovery-suodattimen käyttöön ja sovelluksen käyttöön ja noudattaen paikallisen mukaisesti.

Recovery-suodatinta on säilytettävä viileässä (asennemmassa) ja kuivassa.

Takuu

Bard tekee tuotteen asianmukaisille valmistus- ja laatumaan ole valmistuksen aikana tapahtuneen virheen (-) vuoksi sen ensimmäisen potilaskäytön aikana, ja tämän vuoksi tämän käytön tai sen mukaisen käytön aikana tuotteen korjaamisen tai vaihtamisen yhden omaisuuden mukaan tai maksaen tuotteen hyvitysmäärän. Tämä kirjallinen takuu on koko asiakkaan ainoa ja yksinomainen oikeus tuotteen virheen tai vaurion suhteen.

TÄMÄ TAKUU ETTUTTUOTE ETAKUU KORVAA SOVELTUVIN LAIN PERITTEISSÄ KAIKKI MUUT EIMAINITUT JA KONKLUDENTTISET TAKUUT, MUKAAN LUKIEN MUTTA NIIHIN RAJOITTUMATTA KAIKKI OLETETUT TAKUUT TUOTTEEN KURANTTIUDESTA EN SOPIMUKSESTA TIETTYYN KÄYTTÖTARKOITUKSEEN. BARD EI OLE KIINNISSÄÄN TÄMÄN TAKUUSSA VASTUUSSA MISTÄÄN SATUNNAISISTA TAI EPÄSUORISTA VAHINGOISTA, JOTKA JOHTUVAT TUOTTEEN KÄSITTELYSTÄ TAI KÄYTÖSTÄ.

Joissakin maissa ei hyväksytä tiettyjen takuiden rajoitusten tai ajanjaksojen voimassaolon poissulkemista, joten tämän takuun ei ehkä koske sinua.

Labeling Issue Date: 12-09

Jos tämän päivämäärän ja tuotteen käyttäjäpäivämäärän välillä on kulunut kolme (3) vuotta, käyttäjän tulisi ottaa yhteyttä C. R. Bardiin, hankkiakseen mahdollisia tiedotteita tuotteesta.

Bard, Recovery, ja Recovery Cone ovat C. R. Bard, Inc:n tai sen tytäryhtiön rekisteröityjä tavaramerkkejä.

Yhdysvaltain patentti nro 6,607,558 ja 6,258,026. Muita patentteja myönnetty ja/tai hakemuksessa.

Viitteet

1. ACR Standard For The Performance Of Percutaneous Pulmonary Mechanical Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2010 (Res. 32). Effective 01-01-11.

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RH11 9SP

Recovery Filter System
Système de Filtre Recovery
Recovery Filter System
Sistema del Filtro Recovery
Sistema de Filtro Recovery
Recovery-filter-systeem
Sistema do filtro Recovery
Σύστημα Ανάκτησης Φίλτρου
Recovery Filter System
Recovery-filtersystem
Recovery-suodatinjärjestelmä

Expiration Date
Date de péremption
Verfallsdatum
Data di scadenza
Fecha de caducidad
Vencimento
Prazo de validade
Ημερομηνία λήξης
Udløbsdato
Utgångsdatum
Viimeinen käyttöpäivä

LOT

Lot Number
Numéro de lot
Chargen-Nr.
Lotto numero
Número de lote
Partijnummer
Número do lote
Αριθμός παρτίδας
Lot-nummer
Partinummer
Erän numero

Attention, See Instructions for Use
Attention, voir Mode d'emploi
Achtung, bitte Gebrauchs-Information beachten
Attenzione, leggere le informazioni per l'uso
Atención, Véanse las instrucciones de empleo
Let op, lees de Gebruiksaanwijzing
Atenção, ver Informações de utilização
Προσοχή, Βλέπε Οδηγίες Χρήσης
Bemærk, Se Brugerinformationer
Obs, se bruksanvisningen
Huomio, katso käyttöohjeet

STERILE EO

Sterilized by Ethylene Oxide
Stérilisé à l'oxyde d'éthylène
Mit Ethylenoxid sterilisiert
Sterilizzato mediante ossido di etilene
Esterilizado con óxido de etileno
Gesteriliseerd met ethyleenoxide
Esterilizado com óxido de etileno
Αποστειρωμένο με Οξείδιο του Αιθυλενίου
Steriliseret ved hjælp af ethylenoxid
Sterilisert med etylenoksid
Steriloitu etyleenioksidilla

NON PYROGENIC

Non-pyrogenic
Apyrogène
Pyrogenfrei
Non pirogeno
No pirógeno
Pyrogeenivapaa
Απυρογόνο
Ikke pyrogent
Icke pyrogent
Pyrogeeniton

Single Use. Do Not Reuse.
À usage unique. Ne pas réutiliser.
Nur zum Einmalgebrauch. Nicht wiederverwenden.
Monouso. Non riutilizzare.
De un solo uso. No reutilizar.
Voor eenmalig gebruik. Niet opnieuw gebruiken.
Utilização única. Não Reutilize.
Μίας Χρήσης. Μην Επαναχρησιμοποιείτε.
Engangsbrug. Må ikke genbruges.
För engångsbruk. Får ej återanvändas.
Kertakäyttöinen Ei saa käyttää uudelleen.

Do Not Re-sterilize
Ne pas restériliser.
Nicht resterilisieren.
Non risterilizzare.
No resterilizar.
Niet opnieuw steriliseren.
Não reesterilize.
Μην Επαναποστειρώνετε.
Må ikke resteriliseres.
Omsterilisera inte.
Ei saa sterloida uudelleen.

Sterile, non-pyrogenic unless package is damaged or opened.
Sterile e non pirogeno nella confezione chiusa e intatta.
Steriel et apyrogène sauf si l'emballage est endommagé ou ouvert.
Be unbeschädigter und ungeöffneter Verpackung steril und pyrogenfrei
Estéril y no pirógeno, a menos que el envase esté abierto o dañado.
Do inhoud is steriel en pyrogeenvrij zolang de verpakking ongeopend en onbeschadigd blijft.
Estéril, apirogénico a menos que a embalagem esteja danificada ou aberta.
Στείρα και μη πυρετογόνα εφόσον η συσκευασία δεν έχει ανοιχτεί ή υποστεί ζημιά.
Sterilt og apyrogent, så længe pakningen er hel og ubeskadiget.
Steril och pyrogenfri såvida inte förpackningen skadats eller öppnats.
Steriili ja pyrogeeniton, jos pakkaus on ehjä ja avaamaton.

MRI

MRI compatible; MRI-safe and neither interferes with nor is affected by the operations of an MRI device.
Compatible IRM : Ne présente aucun risque en cas d'IRM, n'interfère pas avec et n'est pas affecté par le fonctionnement d'un dispositif d'IRM.
MRI-kompatibel. MRI-sicher und stört nicht den Betrieb einer MRI-Vorrichtung oder wird von ihr beeinträchtigt.
Compatibile con la procedura di RM: Sicuro per la RM; non interferisce né è affetto dal funzionamento degli strumenti di RM.
Compatible con IRM: seguro para IRM y ni interfiere ni se ve afectado por el funcionamiento de un aparato de IRM.
Geschikt voor MRI: Veilig bij gebruik van MRI en stoort de werking van het MRI-apparaat niet, en wordt evenmin door de werking van het apparaat beïnvloed
Compatível com RM: Seguro em RM e não interfere nem é afetado pelo funcionamento de um dispositivo de RM.
Συμβατό με συσκευές MRI: Είναι ασφαλές από τις διαδικασίες MRI και δεν παρεμβαίνεται στην λειτουργία ή λειτουργία της συσκευής μαγνητικής τομογραφίας.
MRI-kompatibel: MRI-sikkert og hverken påvirker eller påvirkes af brugen af en MR-enhed.
MRT-kompatibel: MRT-säker och varken påverkar eller påverkas av funktionen hos en MRT-anordning.
Magneettiresonanssiin soveltuva ympäristöpiiri: turvallinen käytää magneettiresonanssissa eikä häiritse magneettiresonanssilaitetta, eikä magneettiresonanssilaite vaikuta siihen.

Warning: After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
Mise en garde : Après usage, ce produit est susceptible de présenter un risque biologique. Veiller à le manipuler et à l'éliminer conformément aux pratiques médicales admises et aux lois et réglementations en vigueur.
Warnhinweis: Nach dem Gebrauch kann dieses Produkt eine biologische Gefahrenquelle darstellen. Behandeln und entsorgen Sie das Produkt entsprechend anerkannter medizinischer Praxis und aller anwendbaren Gesetze und Vorschriften.
Attenzione: Dopo l'uso, questo prodotto può costituire un rischio biologico. Maneggiare e smaltire ai sensi della alla pratica medica comunemente accettata e della legge e regolamenti vigenti.
Aviso. Después del uso, este producto puede ser un peligro biológico en potencia. Manipúlelo y deséchelo según la práctica médica aceptable y conforme a las leyes y normas aplicables.
Waarschuwing: Na gebruik kan dit product potentieel besmettingsgevaar opleveren. Behandel het en werp het weg op gangbare medische wijze en volgens de van toepassing zijnde wetten en regels.
Advertência: Após utilização, este produto pode constituir um risco biológico potencial. Manuseie e elimine-o de acordo com a prática médica aceites e normas locais estatais e federais aprovadas.
Προειδοποίηση: Μετά τη χρήση, το προϊόν αυτό ίσως αποτελεί δυνητικό βιολογικό κίνδυνο. Ο χειρισμός και η απόρριψη του πρέπει να γίνονται σύμφωνα με την αποδεκτή ιατρική πρακτική και τους ισχύοντες νόμους και κανονισμούς.
Advarsel. Efter brug kan dette produkt udgøre en potentiel biologisk risiko. Det skal håndteres og bortskaffes i overensstemmelse med godkendt medicinsk praksis og med gældende love og bestemmelser.
Varning: Efter användning kan denna produkt utgöra potentiell biologisk riskmaterial. Hantera och kassera det i enlighet med vedertagen medicinsk praxis och gällande lagar och föreskrifter.
Varoitus: Käytön jälkeen tämä tuote voi olla tartuntavaarallinen. Käsittele tuotetta ja hävitä se sairaalahygienian vaatimusten mukaisesti ja sovellettavien lakien ja määräysten mukaisesti.

Contents: REF: RF-048F Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) Recovery Filter Femoral Delivery System
Contenu: REF: RF-048F Kit A: Un (1) cathéter d'introduction 7 Fr. long de 48cm avec dilatateur Kit B: Un (1) système de mise en place fémorale de filtre Recovery
Inhalt: REF: RF-048F Kit A: Ein (1) 7 Fr. Einführungskatheter, 48 cm lang, mit Dilator Kit B: Ein (1) Recovery Filter Femorale-Einführsystem
Contenuto: RIF: RF-048F Kit A: Un (1) catetere di introduzione da 7 Fr di lunghezza pari a 48 cm con dilatatore Kit B: Un (1) Sistema femorale di applicazione del Filtro Recovery
Contenido: REF: RF-048F Kit A: Un (1) Catéter introductor de 7 Fr. 48 cm de longitud con dilatador Kit B: Un (1) Sistema de liberación femoral del Filtro Recovery
Innhold: REF: RF-048F Sett A: Én (1) 48 cm lange Introdusérkateter Ch. 7 med dilatator Sett B: Én (1) Recovery filter leveringssystem vene for lår femoralis
Conteúdo: REF: RF-048F Kit A: Um (1) cateter introdutor de 7 Fr com 48 cm de comprimento e dilatador. Kit B: Um (1) sistema de liberação femoral do filtro Recovery
Περιεχόμενα: REF: RF-048F Kit A: Ένας (1) Καθετήρας Εισαγωγέα με Μήκος 48 cm και Ε.Δ. 7 Fr. με Διαστολέα, Κιτ Β: Ένα (1) Σύστημα Μηριαίας Απελευθέρωσης Φίλτρου Recovery
Indhold: REF.: RF-048F Kit A: Ét (1) 7 Fr. indføringskateter, 48cm langt med dilatator Kit B: Ét (1) Recovery filter femoralt indføringssystem
Innehåll: REF: RF-048F Satz A: Ein (1) 7 F introducerkateter, 48 cm lang med dilator Satz B: Ett (1) Recovery filtersystem för femoral införing
Sisältö: TUOTE: RF-048F Sarja A: yksi (1) kaksiontelta varustettu 7 Fr sisäänvientiä: pituus 48 cm Sarja B: yksi (1) Recovery-suodatinnen femoraalinen vientisysteemi

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